Ally Qi, MPH
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## EDUCATION

**Vanderbilt University Data Analytics & Visualization Bootcamp Certificate**

Vanderbilt University, Nashville, TN

**Master of Public Health (MPH)**

Touro University California (TUC), Vallejo, CA

Concentration: Global Health & Research

**Bachelor of Science in Human Biology**

University of California-Santa Cruz, Santa Cruz, CA

## WORK EXPERIENCE

**Clinical Trials Manager** *July 2022 – Present*

**Associate Clinical Trials Operations Manager (CTOM)** *Mar. 2021 – Jun. 2022*

Vanderbilt Coordinating Center (VCC), Vanderbilt University Medical Center (VUMC), Nashville, TN

**Trial Management**

- Manage and operationally deliver clinical elements within a trial including site selection, start-up, enrollment management, site engagement and support, monitoring planning and execution, regulatory documentation, data cleaning activities, and close-out
- Perform ongoing regulatory review for participating Clinical Trial sites to maintain compliance with applicable local, and federal legal practices
- Oversee the safety profile of the Clinical Trial by reviewing Serious Adverse Event reports, Protocol Deviations, and other unanticipated events that are reported by

Clinical Trial sites and ensure that events are reported to proper authorities in a timely manner

- Oversee continuous institutional approval and applicable amendments at participating Clinical Trial sites that involve Institutional Review Board (IRB), Contracts, and Grant Offices
- Communicate with the National/Global Principal Investigator, Site Investigator, and/or Clinical Trial committee members as needed regarding trial data by running frequent reports to provide trial updates and identify gaps. Develop and implement corrective action plans to encourage sites to provide complete datasets
- Compile data, reports, and outcome measures to develop reports and presentations for various trial committees and sponsors that show current and future financial, safety, compliance, and enrollment milestones
- Organize, attend, and/or present at committee meetings, collaborator meetings, and internal operational meetings related to the Clinical Trial
- Ensure that participating Clinical Trial sites remain compliant with data submission and other applicable reporting criteria before payments are released to their individual subcontracts

**Data management**

- Responsible for developing, amending, and maintaining electronic data capture systems associated with all aspects of multicenter data collection and study workflow
- Assist with electronic data-capture support where participating sites can receive real-time assistance with regulatory support, clinical questions, and enrollment support
- Identify issues in current datasets and generate queries regarding data accuracy for each participating Clinical Trial site
- Oversee the monitoring process for the electronic data submitted from national Clinical Trial sites which also includes the oversight of Clinical Research Associates (CRAs) who directly monitor trial data. Responsible for the oversight of the project's

monitoring process to ensure data accuracy while incorporating applicable laws and guidance

- Develop and incorporate centralized data monitoring plans and methods to ensure that final trial data is accurate before analysis and publication
- Responsible for identifying, assigning, monitoring, and maintaining appropriate levels of internal and external user access to Clinical Trial databases

**Innovations**

**Data Visualization**

- Build a data pipeline with Python API to develop a PowerBi dashboard to display enrollment and estimated drug inventory status at each participating site in real-time for the NECTAR ACTIV-4 Host Tissue trial
- Build a data pipeline with Python API to develop a PowerBi dashboard to display key study metrics, such as site enrollment status, data completion status, primary outcome metrics, safety events, payment status and study timeline milestones for the FEAT trial

**Project Management**

- Run Python API to extract data from regulatory databases to develop regulatory compliance reports for all participating clinical sites
- Run Python API to extract audit trail logging data from REDCap to develop reports to keep track of data entry progress and query status of all participating clinical sites
- Run Python API to develop CRAs' monitoring progress reports, such as the number of participants CRAs monitored per month, the total number of payments are ready to be released upon CRAs' review, the total number of queries CRAs issued and closed per month
- Automate repetitive data and administrative tasks and create custom functions on Excel spreadsheets by Excel VBA per request
- Prepare unblinded DSMB reports using R for the SOT trial

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**Senior Clinical Research Data Specialist/CRA** *Nov. 2018 – Feb. 2021*

VCC, VUMC, Nashville, TN

- Oversaw data management of multi-site human studies involving pharmaceuticals, biologics, and/or devices
- Maintained effective working relationships with the study team, study PI, and participating sites
- Validated clinical trial data to ensure consistency, integrity, and accuracy based on project-specific guidelines

**Research Analyst III** (Data Management & Database Construction) *Apr. 2016 – Oct. 2018*

General Pediatrics, VUMC, Nashville, TN

- Oversaw data management, provided data analysis support utilizing Stata, and designed & built databases in REDCap & ACCESS
- Generated and presented data reports to the research team, and to the internal and external funding agencies
- Communicated and coordinated with team members to identify reporting needs and to problem-solve ongoing data issues

## PROFESSIONAL DEVELOPMENT

**Publications:**

**1)** Self WH, Shotwell MS, Gibbs KW, et al; ACTIV-4 Host Tissue Investigators. Renin-angiotensin system modulation with synthetic angiotensin (1-7) and angiotensin II type 1 receptor–biased ligand in adults with COVID-19: two randomized clinical trials. JAMA. Published April 11, 2023. doi:10.1001/jama.2023.3546

a. Contribution: site management (e-appendix page 2)

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**2)** Heerman, W. J., Sommer, E. C., Qi, A., Burgess, L. E., Mitchell, S. J., Samuels, L. R., Martin, N. C., & Barkin, S. L. (2020). Evaluating dose delivered of a behavioral intervention for childhood obesity prevention: a secondary analysis. *BMC public health*, *20*(1), 885. https://doi.org/10.1186/s12889-020-09020-w

**3)** J. Heerman, William & E. Burgess, Laura & Escarfuller, Juan & Teeters, Leah & Slesur, Lauren & Liu, Jia & Qi, Ally & Samuels, Lauren & Singer-Gabella, Marcy. (2018). Competency-Based Approach to Community Health (COACH): The methods of a family-centered, community-based, individually adaptive obesity randomized trial for pre-school child-parent pairs. Contemporary Clinical Trials. 73. 10.1016/j.cct.2018.08.006

## TECHNICAL SKILLS

**Tools:** Microsoft Excel VBA, R, Stata, Python, JavaScript, HTML, CSS, Bootstrap, Plotly, D3, Tableau & Power BI

**Databases:** SQL and non-SQL databases (PostgreSQL, MongoDB, REDCap, Veeva)

**Computer skills**: Microsoft Office (Access, Excel, Word, PowerPoint, Publisher)

**Licenses or Certificates**: Emergency Medical Technician license (2012-14), ambulance driving certificate (2012), BLS CPR certificate (2015)