Ally Qi, MPH
Phone: 209-330-3024 | Email: mcally1220@gmail.com | Willing to relocate
LinkedIn: https://www.linkedin.com/in/mcally

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

Site 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/global 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

- Run Python API to extract data from 3 different REDCap databases and build a PowerBi dashboard to display enrollment and drug inventory status at each participating site in real-time
- Run Python API to extract data from regulatory database 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 track data entry progress and open query status by all participating clinical sites
- Run Python API to develop CRAs' monitoring progress reports, such as how many participants CRAs monitored per month, how many payments are ready upon CRA's review, how many queries CRAs issued and/or closed per month
- Built and maintain a PowerBi dashboard to display key study metrics, such as site enrollment status, data completion status, primary outcome metrics, safety events, payment status, study timeline milestones, etc.
- Use Excel VBA to automate repetitive data tasks and create custom functions on Excel spreadsheet per leadership's requests, such as changing folder names, converting site IDs to site names, creating site reports based on certain criteria, etc.

Senior Clinical Research Data Specialist *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 Building) *Apr. 2016 – Oct. 2018*
General Pediatrics, 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

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EDUCATION

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

PROFESSIONAL DEVELOPMENT

Publications:

1) 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

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

TECHNICAL SKILLS

Tools: Microsoft Excel VBA, R, SPSS, STATA, Python (Pandas, Matplotlib, Flask, API, etc.), JavaScript, HTML, CSS, Bootstrap, Plotly, D3, QGIS (Geographic Information System), 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)