CHARLES C. MBATA

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Gilbertsville, PA 19525

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SUMMARY

- Detail-oriented and versatile clinical research professional with excellent knowledge of the clinical trial process, ICH GCPs and FDA Regulations.
- Extensive experience in clinical site activation and study start up process.
- Extensive experience with IRB processes and guideline.
- Extensive experience with clinical data management.
- Extensive experience in all aspects of site management and visits(PSSV, RMV (routine & remote), COV)
- Unique Sponsor and CRO industry experience.
- Broad knowledge of Ethic in clinical research.
- Broad knowledge of Health Insurance Portability and Accountability Act (HIPAA)
- Highly motivated and organized with a flexible attitude
- Able to utilize initiative and work independently as required
- Broad knowledge of medical terminology
- Multi-therapeutic clinical trial experience
- Team oriented professional who consistently meets deadlines even when working under pressure.
- Good Writing and Interpersonal Skills with the ability to communicate effectively and build collaborative relationship with others.

PROFESSIONAL EXPERIENCE

Maxx Orthopedics
Clinical Trial Manager (Medical Device) **DEC 2019-Present**

- Negotiating and managing the budget and the payments
- Vendor KPI & KQI Tracking
- Site recruitment, feasibility, essential document collection and review, clinical status tracking
- Reporting on progress of study including site activation, patient enrollment, monitoring visits
- Writing or contributing to preparation of clinical protocols, amendments, informed consent forms, study guides, case report forms, and any other clinical research related documents
- TMF maintenance
- Performing clinical data review of data listings and summary tables, including query generation
- Overseeing performance of Investigator sites, third party vendors, and field CRAs including co-monitoring, to ensure compliance with study protocol and in accordance with scope of work; identifying areas of concern and escalating to Clinical Director
- Identifying, selecting, and monitoring performance of investigational sites for clinical studies
- Investigating queries, monitoring discrepancies
- Audit Response

Novartis Pharmaceutical Company
Senior Clinical Research Associate **OCT 2016-DEC 2019**

- Perform routine site visits, including Pre-Study, Initiation, Routine and Closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines, and other applicable regulatory requirements, and assurance of good site performance.
- As an interdisciplinary co-lead, I collaborated with other departments (Medical Leads, Medical Science Liaisons, MO on Site Feasibility
- SWAT CRA for other Therapeutic Areas in different regions
- CRA trainings (Protocol, Monitoring Plan etc) at Investigational meetings.
- Manage assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Recruit investigators for participation in clinical trials.
- Negotiate study budgets with investigators/investigative sites
- Obtain, review for appropriateness, and process regulatory and administrative documents from investigator sites.
- Resolve queries of CRF data with the study personnel
- Review Tables and Listings generated from study data.
- Maintain project-tracking systems of subject and site information.
- Participate in company-required training programs.

- Perform necessary administrative functions (e.g. Site payment reconciliation, submission of expense report, entering time)
- Train/Mentor junior CRAs on monitoring, internal procedures, and query resolution.
- Participated in investigator meetings
- Designed action plans for sites (e.g. Recruitment, Data matrix etc).

Inventiv Health Clinical, LLC
Senior Clinical Research Associate **OCT 2014-OCT 2016**

- Perform routine site visits, including Pre-Study, Initiation, Routine and Closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines, and other applicable regulatory requirements, and assurance of good site performance.
- Manage assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Recruit investigators for participation in clinical trials.
- Negotiate study budgets with investigators/investigative sites
- Obtain, review for appropriateness, and process regulatory and administrative documents from investigator sites.
- Resolve queries of CRF data with the study personnel
- Review Tables and Listings generated from study data.
- Maintain project tracking systems of subject and site information.
- Participate in company-required training programs.
- Perform necessary administrative functions (e.g. Site payment reconciliation, submission of expense report, entering time)
- Train/Mentor junior CRAs on monitoring, internal procedures, and query resolution.
- Participated in investigator meetings
- Designed action plans for sites (e.g. Recruitment, Data matrix etc).

INC Research
Clinical Research Associate II **MAY 2014-OCT 2014**

- Perform routine site visits, including Pre-Study, Initiation, Routine and Closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines, and other applicable regulatory requirements, and assurance of good site performance.
- Manage assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Recruit investigators for participation in clinical trials.
- Negotiate study budgets with investigators/investigative sites
- Obtain, review for appropriateness, and process regulatory and administrative documents from investigator sites.
- Resolve queries of CRF data with the study personnel
- Review Tables and Listings generated from study data.
- Maintain project tracking systems of subject and site information.
- Participate in company-required training programs.
- Perform necessary administrative functions (e.g. Site payment reconciliation, submission of expense report, entering time)

RESEARCH PHARMACEUTICAL SERVICES
Clinical Research Associate I **MAY 2010-MAY 2014**

- Participate in site identification and selection process
- Consistently submit study related documents into the Trial Master File, according to Sponsor expectations
- Provide protocol training to Clinical Research Associates that are newly assigned to study project
- Performed assessment visits for newly hired Clinical Research Associates
- Assist Clinical Team Leaders in the review of Site Visit Reports
- Track Screen Failure and Subject Lost to Follow Up reasons/percentage and provide status report to Team Leaders

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- Perform Audit of the Trial Master File and ensure Clinical Research Associate make timely submissions of Trip Report, Follow-up and Confirmation Letters to the Trial Master File.
- Perform Pre study Selection Visit, Site Initiation Visit, Site Monitoring Visit, and Close Out Visit
- Develop collaborative relationship with Sponsor representative and Site Staff
- Identify and resolve site level issues according to Sponsor and RPS Standard Operating Procedures
- Track site recruitment activity; implement appropriate contingency plans as needed and provides update to study team.
- Prepare and submit trip reports within company specified timeline.

ALBERT EINSTEIN HOSPITAL

Clinical Research Assistant **JAN 2008-APR 2010**

- Reviewed patient charts, identified potential research participants and scheduled subject screening visits
- Collected and reviewed regulatory documents for accuracy and completeness, maintaining current and updated documents
- Prepared Source Document Worksheets for assigned Clinical Studies
- Collected data from clinical trial subjects per procedures listed in study protocol
- Responsible for the receipt, acknowledgement, handling, dispensing and accountability of Investigational Products
- Responsible for maintaining inventory of study supplies such as Lab Kits
- Obtained informed Consent from Clinical trial participants.

DEVEREUX FOUNDATION

Treatment Manager **JAN 2003 – DEC 2007**

- Psychiatry Case Management-Bipolar Disorder, Anxiety Disorder, Pediatric Psychiatry, Down Syndrome, Depression
- Medication Reviews, Regulatory reviews, Incident reporting, crisis management 3800/6800 regulations, HCSIS regulation and reporting
- Hiring and orientation, justification of medical necessity for RTF level care, admission evaluation and summation, inter agency meetings, Progress reports
- Managed Care (MBH, CCBH, VO, CBH, CBHNP)

EDUCATION

2015 MASTER'S IN BUSINESS ADMINISTRATION/HEALTHCARE MANAGEMENT (IN PROGRESS)
DEVRY UNIVERSITY
FORT WASHINGTON, PA USA

2009 HEALTHCARE MANAGEMENT CERTIFICATION
WIDENER UNIVERSITY
CHESTER, PA USA

2007 BACHELORS IN EARTH SCIENCE
TEMPLE UNIVERSITY
PHILADELPHIA, PA USA

PROFESSIONAL MEMBERSHIPS

2014 ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

SUMMARY OF PROJECT EXPERIENCE

THERAPEUTIC AREA & SUB INDICATION	*PHASE*	*JOB TITLE*
ONCOLOGY/LYMPHOMA/OVARIAN/MELANOMA/LUNG	I, II & III	CRA
HEART FAILURE	II & III	CRA
CNS/DEPRESSION	II &III	CRA
CNS/ ALZHEIMER'S DISEASE	III & III	CRA
ARTHRITIS (RA & PSA)	II &III	CRA
ARTHRITIS (ANKYLOSING SPONDYLITIS OR NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS)	III	CRA
DERMATOLOGY DISORDER	II & III	CRA

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LIVER DISORDER	II & III	CRA
CNS/BACK PAIN	II & III	CRA
GASTROENTEROLOGY: CROHN'S DISEASE.	II & III	CRA
KNEE REPLACEMENT	IV	CLINICAL TRIAL MANAGER
HIP REPLACEMENT	IV	CLINICAL TRIAL MANAGER
HIP REPLACEMENT REGISTRY	IV	CLINICAL TRIAL MANAGER
OTHER NON-CLINICAL EXPERIENCES: • **FUNCTIONAL CO-LEAD** (NOVARTIS)-RESEARCH DAY @UPENN 2019 • **ORGANIZER** (NOVARTIS)-COMMUNITY OUTREACH PROGRAM @PHILABUNDANCE, PHILADELPHIA 2018		

REFERENCES:
Available upon request

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