MENU

Francisca Chikaodili Diala

Doctorate /Public Health

I have Profound understanding of clinical research methodology and regulations, Excellent presentation and communication skills, Ability to think independently and take initiative, Excellent project management skills, Accelerate operation harmony within the company, Compiled a series of workable protocols that worked closely with study documentation, procedures including biographical materials and approved consent forms, Highly skilled in developing project plans and schedules, Hands on experience in tracking projects and reporting on budget and project status, In depth knowledge of evaluating system solutions and preparing reports for safety monitoring committees and Public health.

ABOUT ME

NAME

Francisca Chikaodili Diala

FOLLOW ME ON

in

MY EDUCATION

Doctorate in Public health
2018-2020

Postgraduate in Nano-biotechnology
2008-2009

Bachelor of science in Biochemistry
1996-2001

Maters in Biomedical engineering
2010

Clinical Research Training
Ethical Issues in Human subject Research; Roles and Responsibilities of the Investigator; Roles and Responsibilities of the Institution; Regulatory Issues e.g. FDA Guidance regarding Clinical Trials, ICH Guideline for Good Clinical Investigators and Mass Media. 2013

Clinical Research Associate
Focus, ICH GCP training, Training for Clinical Research Associate; Focus ICH GCP training includes; Drug development, clinical trials Overview, Legal Basis, MPG, obligations of the test centre, GCP- documents, Registration Authorities, documentation and data management, pharmacovigilance, audit and inspections

WORK EXPERIENCE

Senior clinical trial coordinator at Merck Group Germany -Oct 2018
Supports the Clinical Operations team in the planning, execution, management and surveillance of clinical trials and the Program Team for operational deliverables and the implementation of the clinical development strategy for a project/program. Maintaining the Trial Master File (TMF), inspections of the study documents for completeness, accuracy and compliance and SOPs and regulatory requirements. Also prepare all the oversight. Compilation of the document packages for medication release at study centers, by ensuring the completeness, correctness and that receipt, as well as carried out timeliness. Receipt of central and the country- specific study documents of clinical teams, countries and / or CROs. Collection and verification of the results of study documents for completeness, accuracy and compliance with SOPs and regulatory

requirements, support in obtaining the medication released. Familiar with IRB terminology, approvals, FDA regulations, and Clinical monitoring process in accordance with GCP/ ICH Guidelines SOPs and study protocols. Following up with module inquiries and initiating solutions. Supports the team to ensure high quality study budget planning, budget management, invoice processing, and oversight.

TMF Expert consultant
2018, TMF conference presenter

Clinical research specialist at Abbvie Biopharmaceutical Germany - Aug 2015-Jul 2018
Creating and maintaining the Trial Master File (TMF), inspections of the study documents for completeness, accuracy and compliance and SOPs and regulatory requirements. Compilation of the document packages for medication release at study centers, by Ensuring the completeness, correctness and that receipt, as well as carried out timely. Receipt of central and the country- specific study documents of clinical teams, countries and / or CROs. Collection and verification of the results of study documents for completeness, accuracy and compliance with SOPs and regulatory requirements, support in obtaining the medication released. Familiar with IRB terminology, approvals, FDA regulations, and Clinical monitoring process in accordance with GCP/ ICH Guidelines SOPs and study protocols. Following up with module inquiries and initiating solutions. Make sure that the center documents are updated as necessary and manage and maintenance Study documents. Reporting of document status and communicate issues / problems to the clinical team (CSL / CRA), Tracking of documents and regular alignment with the documents, Care of the documents in auditor- and achievable state Gathering the Investigator Participation and preparation for regulatory audits and QA as well as Inspection Readiness. Therapeutic experience includes: Oncology Phase I- 1V Clinical Drug Trial Experience in Abbvie Biopharmaceutical Germany.

Clinical research associate - Dec 2012-Jun 2014
Monitor Collected reviewed monitoring Reports Assists with safety Reporting and maintain tracking document Track CRFs and communicate any discrepancies / queries with CRAs and site. Performed study start-up for sites by collecting valuable documents and updating start-up supplies, site visits to determine protocol, Edit, review and maintain team travel calendars to reflect changes and routinely post to client and team members. Familiar with IRB terminology, approvals, FDA regulations, and Clinical monitoring process in accordance with GCP/ICH Guidelines SOPs and study protocols. Following up with module inquiries and initiating solutions. Liaison between client databases (CPMS Remote Patient), helpdesk and team. Report and track Serious Adverse Event / AEs and Progress on Regulatory Document collection.

Research assistant at Bioquant - 2011
Laboratory Project Image processing in cell tracking force: (Image Modeling) with Mat-lab and Image j; Particle tracking strategy to determine cellular traction force.

Research Project in University Clinical, Mannheim -2010-2011
Project Radiology Image processing with Mat- Lab

Laboratory work in the Cellzome EMBL Heidelberg- 2008-2009
Laboratory work

Research Project DKFZ (German Cancer Research Centre Heidelberg - 2007-2008
cell cultures: Glioblastoma cells histological sections, staining for Elastic fibers in histological sections, Molecular biology: RNA Isolation RT- PCR etc. Animal Experiment Immortalization, cell counting etc. Immunohistochemical method: Frozen – section, Subcutaneous Tumor injection Determination of Tumor growth in nude mice.

Internship at Heidelbergpharm; Ladenburg Germany - 2007
Internship in the Biology Lab, Animal Experiment: Subcutaneous Tumor Injection to nude Mice.

SKILLS

PROFESSIONAL SKILLS

- Clinical research 100%
- Clinical Trials 100%
- Project Management 100%
- Data Analysis 90%
- Leadership 100%
- Communication 100%
- Academic study 100%
- Health care 90%
- eTMF 100%

MY INTERESTS & HOBBIES

READING, WATCHING FILMS, BASKETBALL

SOME OF MY WORK & CERTIFICATIONS

SOME WORKS

THESIS & PUBLICATIONS

CONTACT

SEND ME A MESSAGE

Name

Email

Subject

Message

SEND!

Thank You!

“The definition of insanity is doing the same thing over and over again, but expecting different results.” You want to be different, click here.”