# Bréoué NAKA

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*With 10 years'experiences in clinical research, I am currently coordinating 2 clinical studies out of 5. I am responsible for giving the progress status during national kick-off meetings and providing support to Start-up team for regulatory submission and Contract team. Based on KPI, I also managed sites issues with priority. Today, I would like to provide my experience to CRO, Medical device or Pharmaceutical companies.*

**Senior CRA – 10 years experiences in clinical research**

## OTHER ABILITIES

### Clinical Studies Regulation

- GCP
- SOP procedures
- International of Conference and Harmonization and Good Clinical Practice certification (ICH-GCP)
- Jardé's Law
- Clinical trial.gov

### Languages

- English level C1

### IT skills

- **Quality**
  - Veeva Vault (eTMF)
- **Software of medical data**
  - Easily
  - Dxcare
  - Clinsight
  - Xcelera
  - Nadis (HIV)
  - Orbis
  - Cora
  - Siclopedia
  - System IWRS Software
  - Office pack
- **eCRF and ePRO**
  - Clinsight
  - Medidata rave/iMedidata
  - Inform
  - Arone
  - Marvin
  - Trialmanager

### Statistics

- R® studio
- SAS®
- Java J2EE certification

### Sport practices

- Hip – Hop
- Rugby Team

## TRAINING

**2022-2023** **Diploma in immunology therapeutic strategy ,**
Medicine's University of Paris Cité

**2020-2021** **Executive Education Certificate, digital transformation in Healthcare**
Harvard Medical School

**2016-2017** **Master Public Health, Clinical Research**
Medicine's University of Lyon

**2015-2016** **Master health, Molecular Therapeutic Interaction,**
Medicine's University of Amiens (UPJV)

## PROFESSIONAL EXPERIENCES

**2021 Ongoing** **CRA Monitor, B&D_Sponsor dedicated @Abbvie, (CRO)**

**Phase III within therapeutic areas :** Immunology-Gastroenterology
**Site Feasibility :** sites selections**,** supplies evaluation
**Site Initiation Visits (SIV)**: Presentation of the protocol to investigators
**Interim Monitoring Visits (IMV):** data sources checking vs e-CRF
**Close Out Visit (COV)**: medicine inventory**,** destructions
**Mentoring :** Support junior CRA
**Project management :** Kick-off meeting for studies advancement, support Study Start-up and Budget team**,** KPI sites issues management and Data Base Lock management

**2020-2021** **CRA Monitor, DocsGlobal_Sponsor dedicated @Amgen, (CRO)**

**Phase II- III – IV within therapeutic areas:** Haematology - Oncology- Neurology- Nephrology
**Site Initiation Visits (SIV)**: Presentation of the protocol to investigators
**Interim Monitoring Visits (IMV):** data sources checking vs e-CRF

- RBSE-RBM-Remote monitoring: 3 times per week
- Data aging : following outstanding queries, pages, eCRF PI'signatures
- Number of centers : 20 centers

**Close Out Visit (COV)**: medicine inventory **,** destructions
**Invoices validation :** extra cost grind based on contract

**2018-2020** **CRA Monitor, Keyrus Biopharma, (CRO)**

**Phase III – IV- RWE within therapeutic areas:** Haematology (Leukemia) Oncology (Throat, Metatastic kidney cancer) , Rare disease (Drepanocytosis)
**Site Initiation Visits (SIV)**: Presentation of the protocol to investigators
**Interim Monitoring Visits (IMV):** data sources checking vs e-CRF

- Monitoring frequency : 3- 4 times per week
- Number of centers : 10-13 centers according projects

**2014-2017** **CRA Monitor, Hospital**

**Phase III-IV within therapeutic areas :**
Haematology (**Venous thromboembolism**)
Oncology **(Herceptin: Brest cancer)**
Infectious disease with medical device
Pharmaco-epidemiology
**Site Initiation Visit (SIV)**: medical device (HCV-TROD) presentation
**Interim Monitoring Visits (IMV):** data sources checking vs e-CRF

- Monitoring frequency : 2- 3 times per week
- Number of centers : 7 centers

**Database:** EGB-SNIRAM analysis with R studio
**Regulatory Affairs:** submission on Clinical Trial.gov platform