

## Amina Bakhti

### SUMMARY

Over 20+ years of experience as a CRA and Site Study Coordinator.  
Currently, acting as a **Freelance CRA**.  
Post graduate diploma in Clinical Research with additional certification in Clinical Pharmacology.  
Experience in coordinating worldwide studies from Phase I to Post Marketing on the field of **Ophthalmology** in accordance with good clinical practices.  
Studies included treatments for wet age-related macular degeneration, geographic atrophy, diabetic retinopathy and glaucoma.  
Performing role of primary masked coordinator.

### MAIN MISSIONS

Guiding research recruitment efforts through medical staff education and training  
Create Standard Operating Procedures for each study or clinical trial  
Maintain source documents and regulatory documentation of clinical trial  
Collect and ensure quality of clinical data filled in (e)CRF  
Monitor health and safety of subjects with frequent contact and ensure subject compliance with the study protocol  
Present adverse event documentation to Principal Investigator and Sponsor where appropriate  
Train, supervise and evaluate study staff in the performance of their duties. Update training module and retrain study staff as required  
Create and maintains database of subject information and generates reports and shipments of data as needed  
Samples management (preparation and sending to centralized laboratory...)

### CORE COMPETENCES

Medidata/Rave, Oracle, IWRS, CTMS, Full Microsoft Office, IATA certification, GCP training

### KEY ACCOMPLISHMENTS

Developed excellence in clinical research studies conduct with a high rate of patient retention.  
Increased patients recruitment rate.

### PROFESSIONAL EXPERIENCE

2008 - Current : Freelance CRA  
2004 - 2008 : Local Clinical Study Coordinator, Lyon, Hematology, Oncology  
2000 - 2004 : Local Clinical Study Coordinator, Lyon, Oncology, Urology

### EDUCATIONAL BACKGROUND

1999 Clinical Research Associate Training, Sup Santé, Lyon, France  
1998 DEA Clinical pharmacology, metabolism and mechanism of action of drugs, Mention AB. University of Nancy I, France  
1997 Master's degree in cellular biology and physiology. Mention AB. University of Lyon I, France