JAMEL **BOUMIZA**

PROJECT MANAGER / SENIOR CRA / MEDICAL WRITER

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PROFESSIONAL OVERVIEW

16 years of experience in the clinical research field. Well qualified physician having worked as a CRA; project manager and medical writer for several years with a solid background in regulatory submissions and trial management in Tunisia and Morocco. Good regulatory and study documents writing skills and a keen attention to details. Good knowledge of diverse pathologies and pharmacovigilance in clinical trials. Exceptional communication and relationship building skills targeted at ensuring team work and building an effective network of clinical investigators in different hospitals and clinics throughout Tunisia.

WORK EXPERIENCE

2006 - Present **XXXXX**

Project Manager / Medical Writer and Reviewer

Project Manager

Trial management and supervising in Tunisia and Morocco in various therapeutic areas such as, Oncology, Haematology, Neurology, and Pneumology. Management and follow-up of regulatory authority applications and approval and study team management in Tunisia.

Medical Writer and Reviewer

Conception and review of synopsis, protocols, case report forms, physician's information leaflet, patient information and consent forms, patient self-reported questionnaires, abstracts, final study report and statistical reports for clinical trials and observational studies.

Senior Clinical Research Associate

Monitoring of clinical studies (phases II and III) and observational studies in Tunisia in several therapeutic areas including, Haematology, Oncology, Pneumology, Gastro-enterology, Pneumology, Rheumatology, Cardiology and Neurology. Broad experience in diverse pathologies (Asthma, Infertility, Alzheimer, Dry eye disease, Hyper blood pressure, Acute coronary syndrome, Dyslipidemia, Acute coronary syndrome, Rheumatoid arthritis, Ovarian cancer…).

Great experience monitoring sites (including pre-study, initiation, routine monitoring and closeout visits) according to protocol, monitoring guidelines, SOPs, GCP and ICH Guidelines. Excellent understanding of SAE reporting, Case Report Forms (CRF) review; queries generation and resolution. Maintenance of study files.

EDUCATION

2017 **IFIS (Clinical Research training institute)**

Pharmacovigilance in clinical and non-interventional trials training

2012

WHODrug and MeDRA medical coding training

2006

CRA training

2000 **Military Hospital of Tunis - Tunisia**

Qualification in cardiology

1999	**University of medicine – Tunisia**
	Medical doctor diploma
LANGUAGES	
	Arabic: as first language
	French: as second language, fluently spoken and written
	English: fluent speaker and writer
OTHER QUALIFICATIONS	
	Proficient in Microsoft Office software (Outlook, Excel, PPT and Word)

Signature

Date 13/05/2024