

Sté Aid'ARC 36, Comba dels Martirs 11570 PALAJA FRANCE



# Jalila BRUMENT 17 years experience in Clinical Research

# SENIOR CLINICAL RESEARCH ASSOCIATE

#### Age: 41 years

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- - PARIS, Normandy, North and North-West of France
  - France and Belgium

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PROFESSIONNAL EXPERIENCE

- Since 1st March 2000 : Clinical Research Associate, Aid'ARC Company, Normandy
- <u>November 1999 to February 2000</u> : Study Corrdinator in Cardiology, Boucicot Hospital, Paris
- <u>May to July 1999</u> : Study Coordinator in Cardiology, Le Havre Hospital, Normandy
- <u>1998</u> : Research experience in Laboratory of experimental Neuropsychopharmacology : Pr Constentin / CNRS Unit - Pharmacological study in Depression - Rouen

# EDUCATION

- June 2017: IFIS: Loi Jardé
- January 2017: IFIS: Clinical investigations within the framework of the CE marking of the medical devices and ISO 14155:2011 norm
- January 2016: IFIS: Training of the new Clinical Trials Regulation (CTR) EU N°536/2014
- March 2015 : MAPI GROUP : Training of Guideline for Good Clinical Practice of ICH Topic E 6 R1, and of Good Epidemiological Practice (GEP), Guidelines for good



pharmaco-epidemiological practices (GPP), International Ethical Guidelines for Epidemiological Study

- June 2013 : SUNNIKAN CONSULTING : Training of "Certificate to train investigators to GCPs"
- April 2013 : SUNNIKAN CONSULTING : Training of "Preparation of an investigational site audit"
- May 2011 : SUNNIKAN CONSULTING : Training of "French and European Regulatory of EC submission regarding drugs and medical devices"
- Since 2008: GLAXOSMITHKLINE: GCP Training: update training every 3 months
- April 2008 : SUNNIKAN CONSULTING : Training of "New European rules in clinical trials"
- April 2004 : SUNNIKAN CONSULTING : Training of "New European rules in clinical trials"
- December 2003 : IFIS, Training of "New European rules in clinical trials"
- 1999 : University of Pharmacy, Caen : Diploma of Clinical Research Associate
- 1998 : University of Rouen, Master's Degree in Cell Biology, Molecular Biology and Physiology

# ADDITIONAL TRAINING

Experience in studies with a medical device

Experience in studies with electronic CRFs: INFORM, RDE, EDC, MARVIN, Datatrack, Oracle RDC, CSOnline, Projection, e-nable...

# LANGUAGE SKILLS

English (working knowledge), French (mother tongue)

SUMMARY OF EXPERIENCE

- Experience in clinical trial monitoring (feasibility studies, initiation, monitoring, and close-out visits), in coordination of investigators sites, in EC submission, in Investigators and hospital financial contracts management, in management of CRA.
- Therapeutics areas of experience: Oncology, Cardiology, Endocrinology, Paediatrics, Gastroenterology, Pneumology, Rheumatology, Gynaecology, Infectiology, Psychiatry, Nephrology, Haematology and Ophthalmology.



# **EXPERIENCE**

#### CARDIOLOGY

Phase	Pathology	Function
III	Medical device: Interventional Cardiology	CRA
III	Myocardial Infarction	CRA
IV	Arterial Hypertension	CRA
IV	Hypercholesterolemia	CRA
IV	Hypercholesterolemia	CRA
III	Arterial Hypertension	CRA
III	Myocardial Infarction	CRA
III	Heart Failure	CRA
III	Heart Failure	CRA
epidemiologic	Infectious Endocarditis	Study-Co
Investigation	Head Fallens	80
III	Heart Failure	SC
Medico-economics study	Intra-arterial Thrombectomy in Ischemic Cerebral Accident	CRA
III	Coronary Artery Disease	CRA
Observational study	Acute coronary syndrome	CRA
III	Medical device: Heart failure with central sleep apnea	CRA

## ENDOCRINOLOGY

Phase	Pathology	Function
III	Diabetes	CRA
III	Diabetes	CRA
PMS	Growth hormone deficiency	SC

## GASTROENTEROLOGY

Phase	Pathology	Function
Pharmaco-epidemiologic Investigation	Gastro-Hepatology	CRA
III	Dyspepsia	CRA
IV	Gastroesophageal reflux	CRA
II	Crohn's disease	CRA
IV	Crohn's disease and Ulcerative Colitis	SC



### **GYNAECOLOGY**

Phase	Pathology	Function
IV	Menauposis	CRA
IV	Medical device: Contraception with intrauterine contraceptive device	CRA
IV	Polycystic Ovary Syndrome	CRA

#### HAEMATOLOGY

Phase	Pathology	Function
III	Idiopathic thrombocytopenic	SC
	purpura	
Observational study	Multiple myeloma	SC

#### INFECTIOLOGY

Phase	Pathology	Function
Temporary	Patients with an immunosupression : Acute	CRA
Emergency Use	Myeloid Leukemia, Acute Lymphoid Leukemia,	
	Bone Marrow Transplant, Renal Transplant,	
	Chronic Granulomateus disease, Aspergillosis,	
	Candidiasis, AIDS	
Pharmaco-	Flu	CRA
epidemiologic		
Investigation		
III	Vaccine / Immunogenicity	CRA
III	Herpes Vaccine with haematologic malignancies	CRA
IV	Sinusitis	CRA
III	Gram-positive Nosocomial Pneumonia / Intensive	CRA
	Care Unit	

#### NEUROLOGY

Phase	Pathology	Function
IV	Depression	CRA
IV	Sleep Disorder	CRA
IV	Cerebrovascular accident	CRA



#### ONCOLOGY

Phase	Pathology	Function
II	Lung Cancer	CRA
III	Pancreas Cancer	CRA
II	Lung Cancer	CRA
Pharmaco epidemio Investigation	Solid tumor or malignant haemopathy	CRA
II	Lung cancer	CRA
III	Lung cancer	SC
I-II	Lung cancer	CRA
Epidemiologic Investigation	Lung cancer	CRA
III	Venous Thromboemboly	CRA
Observational study	Lung cancer	CRA
Pharmaco epidemio Investigation	Cancer with anaemia	CRA
II	Metastatic cutaneous melanoma	CRA
III	Squamous cell carcinoma of head and	SC
	neck	

## ORTHOPEDICS

Phase	Pathology	Function
III	Fracture of tibial plateau	SC

#### PAEDRIATRICS

Phase	Pathology	Function
III	Vaccine	CRA
III	Asthma	CRA
III	Diarrhea	CRA
IV	Infant milk (against skin manifestation)	CRA
PMS	Growth Disturbance	SC
Observational	Infantile Hemangioma	SC
study Observational	RSV Bronchiolitis	SC
study	KSV Bionemonus	SC

## PNEUMOLOGY

Phase	Pathology	Function
III	Acute Pneumopathy	CRA
IV	Asthma	CRA
IV	Asthma	CRA



#### PSYCHIATRY

Phase	Pathology	Function
IV	Adaptation disorders with anxiety	CRA

## **RENAL SYSTEM**

Phase	Pathology	Function
Ш	Renal Transplantation	SC
III	Haemodialysis and cardiovascular disease	CRA
Observational study	Chronic Renal Insufficiency	CRA
Medico economic study	Chronic Renal Insufficiency	CRA
Feasibility study	Renal Insufficiency	CRA

# RHEUMATOLOGY

Phase	Pathology	Function
Pharmaco epidemio Investigation	Vertebral Fracture	SC
IV	Osteoporosis	CRA
II	lLumbosacral radiculopathy	SC
Observational study	Rheumatoid polyarthritis	SC

## **OPHTALMOLOGY**

Phase	Pathology	Function
IV	Diabetic Macular Oedema	SC

Date:

January 16th, 2018

Signature :