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Mrs. Isabelle GAUDIN
23 years experience in Clinical Research

SENIOR CLINICAL RESEARCH CONSULTANT

Address: 36, Comba dels Martirs – 11570 PALAJA – FRANCE

Area :

- **TOULOUSE, Montpellier, Perpignan, Marseille, Lyon, Bordeaux ; South of France**
- **All over France and Europe.**

PROFESSIONNAL EXPERIENCE

Since 1st October 1998: Aid'ARC SARL: Creation of the company / Manager / Study Leader / CRA / Study-Coordinator.

October 97 to Sept.98: SANOFI-AVENTIS (Laboratoires Rhône-Poulenc Rorer): Study Leader in Cardiovascular

May 94 to Sept 97: SANOFI-AVENTIS (Bellon): CRA in Oncology

June 90 to April 94: SANOFI-AVENTIS (Rorer, Pharmuka, Roger Bellon): Medical Rap in Infectiology and Cardiovascular.

EDUCATION

Jun 2017	IFIS	Methods and tools of the quality audit.
Jun 2017	IFIS	Loi Jardé
Jan 2017	IFIS	Clinical investigations within the framework of the CE marking of the medical devices and ISO 14155:2011 norm.
Jan 2016	IFIS	Training of the new Clinical Trials Regulation (CTR) EU N°536/2014
Dec 2015	BOEHRINGER INGELHEIM	GCP Site Staff Training, BICTP Investigational Site Staff Training
Dec 2015	TEVA	GCP Site Staff Training, TEVA standard modules
Nov 2015	CHIESI	GCP Site Staff Training, ICH GCP version 1.0
June 2013	SUNNIKAN CONSULTING	Training of “Certificate to train investigators to GCPs”,

April 2013	SUNNIKAN CONSULTING	Training “Preparation of an audit (CRA and Investigators site)”,
May 2011	SUNNIKAN CONSULTING	Training of “French and European Regulatory of EC submission regarding drugs and medical devices”,
March 2011	REGISTRAT-MAPI	GCP and Epidemiological GCP training
April 2008	SUNNIKAN CONSULTING	Training of “New rules in clinical trials in France”,
April 2004	SUNNIKAN CONSULTING	Training of “New European rules in clinical trials”,
Ongoing, Jan 2008	GLAXOSMITHKLINE	GCP Training: update training every 3 months, since January 2008
December 2003	IFIS	Training of “New European rules in clinical trials”,
1997-1998	SANOFI-AVENTIS	Training of Study Leader, (training realised by the Medical Directors of all therapeutic areas of AVENTIS)
1994 – 1995	Institut Gustave Roussy (IGR)	Training in Oncology
1994	ARCAM	Diploma of Clinical Research Associate
1994	SANOFI-AVENTIS	Oncology Training, (Scientific training of the Oncology Medical Raps of SANOFI-AVENTIS)
1990	University of Châtenay-Malabry	Diploma of Medical Rap
1987-89	University of Caen	1 st year of Pharmacy

ADDITIONAL TRAINING and EXPERIENCE

Experience in study with a medical device

Experience in study without direct benefit

Experience in studies with an electronic CRF: RDC, enable, iMedidata, Inform, Datatrak, birt, ...

Outside of work experience:

- Competitive tennis, hiking, scuba diving
- I lived in west Africa for 2 years.

LANGUAGE SKILLS

English (working knowledge), French (mother tongue), German (I know the basics of German).

SUMMARY OF EXPERIENCE

Experience as CRA: Investigators recruitment and screening, Pre-Study Visits, Initiation Visits, Monitoring Visits and Close-out Visits, Site Coordination, Investigators GCP Training.

Experience as Lead CRA: Clinical trial management (administrative and regulatory initiation of the study, creation of the study monitoring guideline, management of the sites financial contracts, SAEs follow-up), CRAs training and management.

Experience as Study Coordinator: CRF completion, SAE follow-up, study coordination on site (Study worksheets creation, Patients pre-screening help, Patients visits/examinations/blood samples scheduling, tests reports follow-up, medical files update, study drug management, ...).

Therapeutics areas of experience : Cardiovascular, Cardiology, Dermatology, Endocrinology, Gastroenterology, Gerontology, Gynaecology, Haematology, Infectiology, Neurology, Oncology, Ophthalmology, Pneumology, Psychiatry, Renal System, Rheumatology.

CARDIOLOGY		
Phase	Pathology	Function
III	Arterial Hypertension	CRA
III	Myocardial Infarction (2 sites / 40 patients)	CRA
III	Acute Myocardial Infarction	CRA
IV	Hypercholesterolemia	CRA
IV	Hypercholesterolemia	CRA
IV	Arterial Hypertension	CRA
Epidemiology Survey	Infectious Endocarditis	CRA
IV	Inferior Limbs Arteriopathy	CRA

CARDIOVASCULAR		
Phase	Pathology	Function
III	Thrombosis	Lead CRA
III	Orthopedic Surgery	Lead CRA
IV	Orthopedic Surgery	Lead CRA

DERMATOLOGY		
Phase	Pathology	Function
II	Psoriasis	CRA

ENDOCRINOLOGY		
Phase	Pathology	Function
III	Diabetes	CRA
III	Diabetes / Children	CRA
Post-marketing study	Growth disturbance / Children and Adolescents	Study-Co
Post-marketing study	Growth disturbance / Adults	Study-Co

GASTROENTEROLOGY		
Phase	Pathology	Function
III	Dyslipaemia	CRA
III	Dyspepsia	CRA
IV	Gastroesophageal reflux	CRA
Retrospectiv observational study	Crohn's disease and Ulcerative colitis	Study-Co
III	Colonoscopy	Study-Co

GERONTOLOGY		
Phase	Pathology	Function
II	Sarcopenia	CRA

GYNAECOLOGY		
Phase	Pathology	Function
IV	Medical device: Contraception with intra-uterine contraceptive device	CRA

HAEMATOLOGY		
Phase	Pathology	Function
II	Non Hodgkin's Lymphoma	CRA

INFECTIOLOGY		
Phase	Pathology	Function
Temporary Emergency Use	Patients with an immunosuppression : Acute Myeloid Leukemia, Acute Lymphoid Leukemia, Bone Marrow Transplant, Renal Transplant, Chronic Granulomateus disease, Aspergillosis, Candidiasis, AIDS	Study-Co
I (without direct Benefit)	Medical device: Cystic Fibrosis (children, young adults)	CRA
Retrospectiv study	Hepatitis C Virus Infection	Study-Co
III	Hepatitis C Virus Infection / Depression	CRA
IV	Flu	CRA
III	Varicella-Zoster Virus / autologous haematopoietic stem cell transplant	CRA

III	Varicella-Zoster Virus / haematologic malignancies	CRA
IIIb	Vaccination study / Varicella-Zoster Virus	Study-Co
IIIb	Vaccination study / Varicella-Zoster Virus	Study-Co

NEUROLOGY		
Phase	Pathology	Function
III	Epilepsia	CRA

ONCOLOGY			
Phase	Pathology	Study Title	Function
III	Breast Cancer	A randomized, open label, controlled trial of a chemotherapy to a chemotherapy association in subjects with a metastatic breast cancer, relapsed to a 1 st chemotherapy with Anthracycline	CRA
II	Colorectal Cancer	A randomized, open label, controlled trial of two chemotherapy, with or without 5FU in subjects with an advanced or metastatic colorectal cancer.	Lead CRA
IV	Prostate Cancer	Effect of a Clodronic Acid in subject with a metastatic prostate cancer.	CRA
III	Lung Cancer	A randomized, open label, controlled trial of a chemotherapy association to another chemotherapy association in chemotherapy naïve subjects with a lung cancer.	CRA
III	Colorectal Cancer	A randomized, open label, controlled trial of a chemotherapy 5 days by oral route to the same chemotherapy 21 days by oral route to the chemotherapy, in second line, in subjects with a colorectal carcinoma.	CRA
III	Lung Cancer	A randomized, open label, controlled trial of a chemotherapy by oral route to the same chemotherapy IV, in second line, in subjects with a lung cancer, relapsed 90 days after the 1 st line of chemotherapy.	CRA
II	Lung Cancer	A randomized, open label, controlled trial of a chemotherapy association to another chemotherapy association in subjects with a lung cancer stade IV.	CRA
II	Lung Cancer	A randomized, open label, controlled trial of a chemotherapy and concomitant radiotherapy after an induction chemotherapy to a chemotherapy association in subjects with a locally advanced lung cancer.	CRA
II	Lung Cancer	A randomized, open label, controlled trial of an induction chemotherapy followed by a chemotherapy/radiotherapy to a chemotherapy/radiotherapy followed by an healing chemotherapy in subjects with a lung cancer, no resectable stade III.	CRA
III	Pancreas Cancer	A randomized, open label, controlled trial of a chemotherapy to chemotherapy association in subjects with a locally advanced and metastatic pancreas cancer.	Study-Co

II	Lung Cancer	A randomized, open label, controlled trial of a chemotherapy association to a chemotherapy in old fragile subjects with a stade IV and IIIB (T4 Pleura) lung cancer.	CRA
Pharmaco epidemio Investigation	solid tumor or malignant Haemopathy	Effect of an Epoetin beta in subjects who received an antitumoral treatment with a solid tumor or a malignant Haemopathy	CRA
Retrospectiv study	Colorectal Cancer with hepatectomy	Study to evaluate the hepatic toxicity in subjects with a treatment by chemotherapy with or without a specific chemotherapy.	CRA
II	Lung cancer	A randomized, open label, controlled trial of a modification of the chemotherapy after 2 cycles to a classic chemotherapy in subjects with a stable disease, with a diffused lung cancer.	CRA

I	Colorectal cancer	In metastatic colorectal cancer.	CRA
III	Lung cancer	An international, randomized study.	CRA
Pharmaco epidemio Investigation	Colorectal cancer	In metastatic colorectal cancer.	CRA
Epidemiology study	Lung cancer	An European, observational study	CRA
I	Lung cancer	An international, randomized study with immunotherapy	CRA
III	Prostate cancer	An international, randomized study.	CRA
III	Lung cancer	An international randomized study in subjects with Stage IV/recurrent Non Small Cell Lung Cancer	Study-Co
III	Lung cancer	An international randomized study in subjects with inoperable Stage IV or recurrent non-squamous NSCLC	Study-Co
II	Lung cancer	An international, randomized study with immunotherapy	CRA
III	Prostate Cancer	An international Follow-up study.	Study-Co
I, IIa	Glioma	Unresectable high grade Glioma	CRA

OPHTHALMOLOGY

Phase	Pathology	Function
Observationnal Study	Glaucoma	CRA
III	Myopia	CRA

PNEUMOLOGY

Phase	Pathology	Function
III	Acute Pneumopathy	CRA
IV	Asthma	CRA
IV	Chronic Obstructive Pulmonary Disease	CRA

III	Uncontrolled Asthma	Study-Co
III	Uncontrolled Asthma	Study-Co
III	Chronic Obstructive Pulmonary Disease	Study-Co
III	Chronic Obstructive Pulmonary Disease	Study-Co
III	Uncontrolled Asthma and elevated blood Eosinophils	Study-Co
IIIb/IV	Severe Asthma and uncontrolled Eosinophils	Study-Co
IIIb	Persistent Asthma	Study-Co
IIIb	Chronic Obstructive Pulmonary Disease	Study-Co
III	Severe Asthma and uncontrolled Eosinophils	Study-Co

PSYCHIATRY		
Phase	Pathology	Function
IV	Depression	CRA
IV	Adaptation disorders with anxiety	CRA

RENAL SYSTEM		
Phase	Pathology	Function
Temporary Emergency Use	Renal Transplant	Study-Co
Epidemiology study	Chronic renal insufficiency	CRA
Medico economic and Quality of life study	Renal Transplant	CRA
Update of medical data	Dialysis	Study-Co

RHEUMATOLOGY		
Phase	Pathology	Function
III	Rheumatoid arthritis	Study-Co
IV	Osteoporosis	CRA

Date: November 10th, 2017

Signature: