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Carole DELAUNAY

SENIOR CLINICAL RESEARCH ASSOCIATE
Lead CRA
Expert in Medical device

Age : 36 years
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Mob : +33 6.15.36.34.37
Area : **France, Europe, all over the world.**

PROFESSIONNAL EXPERIENCE

Since February 2007 : CRA in the company Aid'ARC
November 2006 to January 2007 : CRA in the CRC-INSERM-Rouen University Hospital.

EDUCATION

2017	IFIS "Training on the Law of 5 March 2012 known as Jardé, since the publication of Decree 2016-1537 of 16 November 2016 and the publication of the revision of Good Clinical Practice (ICH E6 (R2)."
2016	IFIS: Training "new European regulation for Clinical trial"
2013	SUNNIKAN CONSULTING : training "audit preparation at investigator site"
2011	SUNNIKAN CONSULTING: Training: "clinical research: French requirement" and "clinical research for devices in France"

2008 SUNNIKAN CONSULTING : Training of "New rules in clinical trials in France"

2006 D.U. Recherche et Développement clinique des Médicament: Diploma Approval on Clinical Research with ICH

2006 1st year of MSc specialising in Ethology, Ecology and Evolution of Populations, passed with C grade.

2005 BSc degrees specialising in Biology of Organisms and Populations in University of Rennes1, passed with D grade.

2000 Baccalaureate of A levels specialising in Sciences with special emphasis in Biology.

LANGUAGE SKILLS

English :good working knowledge: (written and spoken), French (mother tongue), Spanish (basic knowledge).

SUMMARY OF EXPERIENCE

Experience in clinical trial monitoring (feasibility studies, investigators screening, initiation and monitoring and closeout visits, in coordination of a study.
Part of the project team as Lead CRA, involved in site management working in cooperation with local CRAs, Project Manager and other study divisions such as Safety , Data Management, Regulatory, legal , etc to ensure compliance to GCP/ICH /ISO and site performance. Review of study documents (Protocol, ICFs, Monitoring Plan, CRF, etc), creation of tools for CRAs.

Audit and inspections experience:

- as site monitor- on site audit: Sponsor audit preparation and support during audit for 2 sites: Medical devices with device accountability in Cardiology and Neurovascular.
- as site monitor- review of the TMF and my dedicated site ISF by Japanese regulation and FDA for premarket study in Neuromodulation with device accoutability.
- As support/reviewer at site: Spain, Austria, France at site (sponsor audit, FDA inspection)
- As support/reviewer -remotely as Lead CRA: Australian EC inspection, Israelian MoH inspection.

Therapeutics areas of experience : **Cardiology (Arterial Hypertension, Myocardial Infarction, Endocarditis, Heart failure), Dermatology (Scleroderma), Endocrinology (Diabetes), Gastroenterology (Oesophageal reflux), Nephrology (Renal failure / dialysis), Neurology (Epilepsia/Aneurysm/Parkinson Disease/Dystonia), Oncology (Breast Cancer), Rheumatology (Rheumatoid arthritis / Rheumatoid spondylitis) , Surgery (Knee surgery). Cardia Rhythm Management (Pacemaker) , Cardiac Surgery (Valves)**

CARDIOLOGY

Phase	Pathology	Detail of activities
IV	Arterial Hypertension	- Investigators screening

		- Creation of the study documents (flow chart, study summary, PIC, CRF, forms, newsletters, ...) - Management of the regulatory and adminitrativ file (CPP, AFSSAPS, CNO) - Screening and training of Study-Nurses - Management of the study logistics - Initiation visits - Monitoring
Observational Study	Myocardial Infarction	Monitoring or Sites coordination (as Study-Nurse)
Investigation	Endocarditis	Sites coordination (as Study-Nurse)
III	Device (stent) Myocardial infarction	Initiation, Monitoring and Close-Out Visits
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III	Device (stent) Myocardial infarction	Monitoring Visits
III	Device (stent) Myocardial infarction	Initiation, Monitoring
III	Device (stent) Myocardial infarction	Initiation, Monitoring
IV	Heart failure and sleep troubles	Pre-study Visits
premarket	Device (algorythm for pacemaker)	Monitoring, closeout
postmarket	Device (cardiac valves)	Monitoring

DERMATOLOGY

Phase	Pathology	Detail of activities
I	Scleroderma	- Creation of a specific medical record for the patients included in the study, by the Phase I Center. - Work on the patients medical records

ENDOCRINOLOGY

Phase	Pathology	Detail of activities
III	Diabetes	- Investigators help in the patients screening - Creation of a specific medical record for the patients included in the study, by the Phase I Center.

GASTROENTEROLOGY

Phase	Pathology	Detail of activities
IV	Oesophageal reflux	Initiation, Monitoring and Close-Out Visits

NEPHROLOGY

Phase	Pathology	Detail of activities
Retrospectiv	Severe renal failure	Record in a e-CRF of the data of patients in dialysis

study	(Dialysis)	

NEUROLOGY

Phase	Pathology	Detail of activities
I without BID	Epilepsia	Creation of a specific medical record for the patients included in the study, by the Phase I Center.
IV	Aneurysm (Neurovascular)	Monitoring visit, closeout visits and activities. Submission to Frenh EC and CA for protocol amendment, safety report and End of study in France and UK.
III	Parkinson Disease (Neuromodulation)	French submission to EC/ CNOM, Site Qualification, management of site logistic. Initiation Visit, .Monitoring visit, closeout visit including device accountability, reconciliation at end of study.
IV	Failed Back Surgery Syndrome (Neuromodulation)	Monitoring visits, closeout visits, End of study submission, Study Monitoring visits, closeout visits, End of study submission, Study report submission. Site manager for OUS sites: ensure compliance with ICH/GCP, local regulation in Quebec, UK, Spain and France with 3 CRAs, review reports, coordination between CRAs and Project team (PM, safety, Data Management)
III	Back Pain (Neuromodulation)	Site Management as Lead CRA: coordination of devices stock at study level, review of the shipment requested by site. : ensure compliance with ICH/GCP, local regulation in Australia, Spain and Belgium with 3 CRAs project support with UAT test for study e-crf, creation of study specific document, review of protocol.
IV	Parkinson Disease (Neuromodulation)	Site Management as Lead CRA :Responsible for the performance of assigned sites in accordance with Good Clinical Practice (GCP), ICH guidelines and local regulations. Responsible for operational aspects of planning and management of site performance in Europe, Canada, Columbia with 12 CRAs. Project support with review and /or creation of study documents (ICF/protocol /monitoring plan/CRF). Budget creation. Contact with Marketing for nominated sites and new countries.
IV	Dystonia (Neuromodulation)	Project support with review and creation of study documents (ICF/protocol /monitoring plan, CRF). Contact with Marketing for nominated sites and new countries

ONCOLOGY

Phase	Pathology	Detail of activities
Pharmaco epidemio Investigation	Breast Cancer	Initiation Visits
Observational study	Breast Cancer	Site Coordination

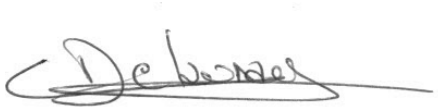
RHEUMATOLOGY

Phase	Pathology	Detail of activities

Retrospectiv study	Rheumatoid arthritis / Rheumatoid spondylitis	Data collection

SURGERY

Phase	Pathology	Detail of activities
III (international)	Knee surgery	Monitoring.



Date : 24 MAY 2017 Signature :