

## ABOUT ME

I am a senior clinical research specialist with 25-year experience in interventional and non-interventional research in an international environment.

## CONTACT

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00 33 7 50 52 14 45

Sophia Antipolis



15 minutes from French third international airport.

## EDUCATION

### FACULTY OF SCIENCES NICE

Master in Pharmacology  
(2000)



Research degree in  
Pharmacology  
(2000)

## CATHERINE BOSC

### CLINICAL RESEARCH CONSULTANT

### BACKGROUND

Prior to founding my consultancy company, Tailorpharma, I have gained experience in research for 13 years, at different positions in pharmaceutical companies. I have worked on drugs and medical devices.

I was in **Galderma R&D Corporate** for 3 years as a Clinical Project Manager in the Medical Affairs Department. I was in charge of projects worldwide, phase I to IV, support to products life cycle management. Before, I spent 3 years in **Sanofi Pasteur MSD Corporate** as a Clinical Operations Coordinator managing European clinical trials, phase III to IV, commitments to post marketing authorization and supporting variations. Eventually, I also spent 6 years, 4 of which in **Bristol Myers Squibb**, as a Clinical Research Associate. I was managing local Investigative sites in oncology, cardiovascular diseases, psychiatry and immunology.

### AN UNIQUE APPROACH FOR DEVELOPING CRA SKILLS

Lead and training of CRA using an innovative method aimed at developing the operational skills of junior and senior CRAs through work situations recreated in a virtual monitoring environment.

Personalized training tailored to the skills the CRA need to practice .

### EXPERIENCE

#### LCRA

*CRA team management, CRA QC visits, mentoring of junior CRA*

#### SITE MANAGEMENT

*Site feasibility and recruitment, contracts with institution, monitoring from site initiation to closure.*

#### PROJECT MANAGEMENT

*Project & team's management and lead. Budget and timelines.*

*Areas of expertise: Interventional and non-interventional studies, CRO and Sponsor environment.*

2026		
CRA Trainer	CRA's support and development	
LCRA	<b>Hematology</b> (phase 2), biotechnology company 8 CRA across 4 EU countries, CTIS submission, investigational site's contract, vendors management, study documents and study plans review	
2025		
Clinical Trial Manager	<b>Hematology</b> (phase 2), biotechnology company CTIS submission, investigational site's contract, LCRA activities (8 CRA across 4 EU countries), vendors management, study documents and study plans review	
CRA Trainer	CRA's support and development	
CRA	<b>Hematology</b> (phase 1/2 Central Nervous System Lymphoma), biotechnology company France 4 sites: initiation, site management and monitoring	<b>Lung Cancer</b> (Non-Small Cell Lung Cancer) phase 1/2, biotechnology company France 3 sites: initiation, site management and monitoring
2024		
CRA Trainer	CRA's support and development	
CRA	<b>Hematology</b> (phase 1/2 Leukemia, Myelodysplastic syndrome), biotechnology company France 3 sites: initiation, site management and monitoring	<b>Hematology</b> (phase 1/2 Central Nervous System Lymphoma), biotechnology company France 4 sites: initiation, site management and monitoring
	<b>Lung Cancer</b> (Non-Small Cell Lung Cancer) phase 1, biotechnology company France 3 sites: initiation, site management and monitoring	<b>Ovarian Cancer</b> (Low-Grade Serous Ovarian Cancer) phase 3, biotechnology company France 6 sites: initiation, site management and monitoring
2023		
Clinical Trial Manager	<b>Ophthalmology</b> (phase 3), pharmaceutical company 20 sites, 360 patients: vendors management, submission packages review, study documents and study plans review, CRA team management (10 CRA across 5 EU countries)	
Lead CRA	<b>Oncology and Hematology</b> (phase 3 DLBCL, phase 1 ovarian and uterus cancer), biotechnology company LCRA activities 21 CRA across 11 EU countries, support to Project Lead, assessment of CRA	
CRA	<b>Hematology</b> (phase 1/2 Leukemia, Myelodysplastic syndrome, Lymphoma), biotechnology company France 4 sites: initiation, site management and monitoring	
	<b>Hematology</b> (phase 1/2 Leukemia, Myelodysplastic syndrome), biotechnology company France 3 sites: initiation, site management and monitoring	<b>Hematology</b> (phase 1/2 Central Nervous System Lymphoma), biotechnology company France 1 site: initiation
2022		
Project Manager	<b>Ophthalmology</b> (clinical investigation medical device), medical device and pharmaceutical company 6 sites, 100 patients: protocol and study documents development	
Lead CRA	<b>Oncology and Hematology</b> (phase 3 DLBCL, phase 1 ovarian and uterus cancer), biotechnology company LCRA activities 21 CRA across 11 EU countries, support to Project Lead, assessment of CRA	
Study Start Up Specialist	France Phase 3: amendments submission to ethics committee France Phase 1: study initial submission to ethics committee, Data privacy, site contracts including CNOM.	France Medical Device clinical investigation: initial submission ethics committee and competent authority
Medical writer	<b>Ophthalmology</b> (clinical survey): poster and manuscript development	

2021			
Project Manager	<b>Ophthalmology</b> (clinical survey), medical device and pharmaceutical company 100 sites, 3500 patients: protocol and study documents development, regulatory package (data privacy), project daily management		
Lead CRA	<b>Oncology and Hematology</b> (phase 3 DLBCL, phase 2 colorectal cancer), biotechnology company LCRA activities 21 CRA across 11 EU countries, support to Project Lead, assessment of CRA		
Study Start Up Specialist	France Phase 2 study initial submission and amendments: ethics committee, Data privacy, site contracts including CNOM.	Phase 3: site contracts including CNOM.	
	France Phase 1 study initial submission and amendments: ethics committee, Data privacy, site contracts including CNOM.		
CRA	<b>Oncology</b> (phase 2 colorectal cancer), biotechnology company France 5 sites: site initiation and monitoring	<b>Hematology</b> (phase 3 DLBCL), biotechnology company France 8 sites: site initiation and monitoring	
	<b>Oncology</b> (phase 1 bladder cancer), biotechnology company France 1 site: site initiation		
2020			
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.	Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.	
	<b>Orthopedics</b> (observational study medical device), medical device company 2 sites, 60 subjects, France: protocol development, start-up activities and project conduct up to report		
Study Start Up Specialist	France, observational study initial submission and amendment: ethics committee, French Data privacy, Notification to ANSM, site contracts including CNOM.	UK observational study initial submission and amendment: ethics committee, HRA, site contracts, UK portfolio adoption	
	Phase 2 study initial submission and amendments: French ethics committee, French Data privacy, site contracts including CNOM.		
CRA	<b>Neurology</b> (phase 3 insomnia), international CRO France 3 sites: monitoring and site closure	<b>Oncology</b> (phase 2 colorectal cancer), biotechnology company France 5 sites: site initiation and monitoring	<b>Hematology</b> (phase 3 DLBCL), biotechnology company France 14 sites: site selection
2019			
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.	Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.	
	France, phase 1 and phase 3 studies, initial submission to ethics committee	France, observational study initial submission and amendment: ethics committee, French Data privacy, Notification to ANSM, site contracts including CNOM.	UK observational study initial submission and amendment: ethics committee, HRA, site contracts, NIHR UK portfolio adoption
CRA	<b>Neurology</b> (phase 3 insomnia), international CRO France 3 sites: monitoring		

2018			
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.		Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.
	<b>Orthopedics</b> (clinical investigation medical device), medical device company 2 sites, 100 subjects: protocol development, start-up activities and project conduct up to report		<b>Ophthalmology</b> (observational prospective study), medical device and pharmaceutical company 4 sites, 60 subjects: protocol development, start-up activities (site selection, contract, submissions for authorization) and project conduct
Study Start Up Specialist	UK Phase 3 initial submission: ethics committee, HRA, competent authorities, site contracts UK, NIHR portfolio adoption	Germany Phase 3 initial submission ethics committees	France Phase 3 and medical device initial submissions: ethics committee, French Data privacy, site contracts including CNOM. Belgium Medical device initial submissions Ethics Committees
CRA	<b>Neurology</b> (phase 3 insomnia), international CRO France 3 sites: site selection, monitoring	<b>Neurology</b> (phase 3 ICU), international CRO France 10 sites: site selection	<b>Cardiology</b> (phase 3, HTA) France 8 sites: site selection
Medical writer	Clinical Evaluation Reports (orthopedic medical devices)		

2017			
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.		Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.
	<b>Ophthalmology</b> (market survey), pharmaceutical company 4 sites, 1000 patients, protocol questionnaire, authorization (data privacy), conduct, data analysis, poster and publication		<b>Ophthalmology</b> (clinical investigation medical device), medical device and pharmaceutical company 3 sites, 50 subjects: protocol development and project conduct up to report
Study Start Up Specialist	France food supplement and medical device: submission ethics committee, competent authorities, French Data privacy, site contracts including CNOM.	UK Medical device initial submission: ethics committee, HRA, and competent authorities	Germany Phase 3 initial submission ethics committees
Medical writer	Clinical Evaluation Reports (orthopedic medical devices)		Expert scientific report: cosmetic ingredient, pre-clinical and clinical data
	Market survey, ophthalmology: communication (paper accepted in Journal Français d'Ophthalmologie Sep. 2017, oral communication for KOL at Société Française d'Ophthalmologie May 2016 and poster)		Development of pediatric consents

2016				
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.		Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.	
	<b>Ophthalmology</b> (market survey), pharmaceutical company Protocol questionnaire, authorization (data privacy), conduct, data analysis, poster and publication			
CRA	<b>Oncology</b> (phase 2 head neck cancer) international CRO 3 sites, France: monitoring	<b>Hematology</b> (phase 2), international CRO 5 sites, France: site selection	<b>Immunology</b> (phase 2), international CRO 4 sites, France: site selection	<b>Rheumatology</b> (phase 3), international CRO 5 sites, France: site selection
Regulatory consultant	External consultant for French Competent Authorities (ANSM)			
Study Start Up Specialist	France Phase 2 initial submission ethics committee and competent authorities, French Data privacy, site contracts including CNOM.		UK Phase 2 initial submission ethics committee, HRA and competent authorities	
Scientific communication	Expert board, medical device: data analysis, presentation development			
2015				
Project Manager	Cardiology (observational global study, rare disease), academic society 40 countries Europe, 130 sites, 1.000 subjects: protocol development, start-up activities, and project conduct up to report and publication.		Cardiology (observational prospective study), academic society 70 countries worldwide, 360 sites, 10.000 subjects: protocol development, start-up activities and project conduct up to report and publication.	
CRA	<b>Oncology</b> (phase 2 head neck cancer) international CRO 3 sites, France: monitoring			
Study Start Up Specialist	Germany Observational study initial submission ethics committee.	UK Observational study initial submission ethics committee. HRA	France Phase 1 initial submission ethics committee and competent authorities	Belgium Phase 1 initial submission ethics committee and competent authorities
Regulatory consultant	External consultant for French Competent Authorities (ANSM)			
2014				
CRA	Oncology (phase 2 colorectal cancer), biotechnology company France 3 sites: monitoring		Orthopedics (non-interventional study), medical device company France 2 sites: site management and monitoring	
Study Start Up Specialist	France Medical device and phase 4 pass studies initial submission ethics committee and competent authorities	UK Phase 4 pass study initial submission ethics committee, HRA and competent authorities	Italy Phase 4 pass study initial submission ethics committees	
Scientific communication	Expert board, medical device, prosthesis: data analysis, presentation development		Expert board, drug, vaccines: support development, minutes and follow up.	

2013		
CRA	Oncology (phase 2 colorectal cancer), biotechnology company France 3 sites: monitoring	Orthopedics (non-interventional study), medical device company France 2 sites: site management and monitoring
Learning	Pharmaceutical company: development of training supports for standard operating procedures	Clinical regulation intelligence: training of clinical team on updated trial regulation in France.

2010-2013	
Clinical Project Manager	Galderma
2007-2010	
Clinical Operation Coordinator	Sanofi Pasteur MSD
2000-2007	
CRA	BRISTOL MYERS SQUIBB CHU SANT ETIENNE