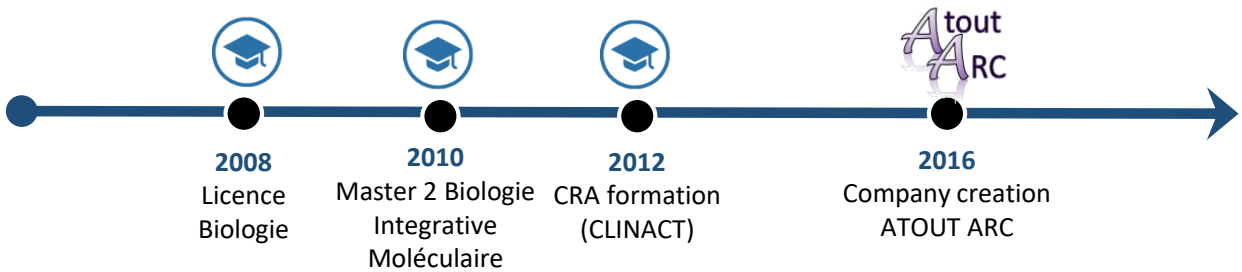




Stéphanie GERMOND
Freelance Sr CRA

With 8 years experience in clinical research, I'm a freelance CRA since 2016 with my company ATOUT ARC to support you with individual services. My autonomy and my expertise in clinical research were acquired in institutional studies or international industrial studies in several therapeutic areas, like oncology or cells therapy . Motivated, reactive and committed to producing quality work, I will support you in a confidentiality and ethic environment, with rigor and flexibility principles.



Services

Investigator support

- CRF entry
- Patients selection
- Site coordination

Monitoring activity

- Monitoring (on site, remote, pharmacy)
- Selection
- Site initiation visit
- Close-out visit
- Site motivation
- Recruitment optimization

Support Study Management

- Contract negotiation / grid cost evaluation
- Feasibility
- Translation of study documents
- Tracker creation
- EC submission (initial, amendment, end of study)

Expertise

Therapeutic areas

- Oncology (all solid tumors and myeloma)
- Cells therapy
- Orthopedics
- Dermatology

Phases

- Early phases
- Phase II and III
- Cohort

Industrial studies (CRO, laboratory, biotech)

- 5 years experience
- more than 10 local and international studies

Hospital environment

- 3 years experience
- More than 50 local and international studies



Stéphanie GERMOND

Freelance Sr CRA

Professional experiences

2011 - 2012

SSC (HEGP-Paris)

*Digestive oncology
Phase II and III*

Patients selection, eCRF entry,
blood samples sending, site
coordination

2012

SSC (Hôpital Raymond Poincaré - Garches)

*Fabry disease
Cohort*

Patients selection, eCRF entry, blood
samples sending, site coordination

2013

CRA (Inventiv Health)

*Myéloma
Phase III*

- Site monitoring, remote monitoring,
pharmacy monitoring (1 study, 9 sites, 5-
6 monitoring visit per month)

2013 - 2014

Study start-up (Inventiv Health for Novartis)

*Dermatology, infectious disease
Phase III*

- EC submission (initiale,
amendment, end of study)
- Document translation, review of
documents

2014-2015

CRA data entry (Unicancer)

*Cancer du sein
Cohort*

Data entries of 2000 cases as part
of a medico-economic national
cohort

2015-2016

SSC (Institut Bergonié - CLCC)

*Oncology
Early phase*

- Patients selection, eCRF entry, blood
samples sending, site coordination
- contract negotiation: evaluation of
additional costs, grid cost evaluation
and negotiation with the sponsor

2017

Freelance CRA

*Ovarian and breast
cancer
Cohort*

Data entries of 500
cases as part of a
medico-economic
national cohort

Since 2017

Freelance CRA

Othopedics – cell therapy (Biotech)

- Site and pharmacy monitoring / Site initiation visit /
Close-Out Visit: phase III about autologous osteoblastic
cells implantation in osteonecrosis of the femoral head (2-
3 monitoring visit per month / 4 active sites)
- Contract negotiation / grid cost evaluation / patient
fees: review and finalization of the hospital contract
(single contract); draft, review and finalization of the grid
cost (under the PM responsibility), discussion and
negotiation with the site, patient fees FU
- Feasibility and site selection visit for a study in tibial
fracture at risk of DU/NU.
- Congress participation (GECO, SOO, HIP Toulouse)
- Patient fees reimbursement, site coordination, tracker
creation

Since 2018

Freelance CRA

*Cardiology
Phase IV*

- Monitoring (1 site, 4
monitoring visits in 10
years)
- Post-AMM study on
cardiac stent (medical
device)

Skills

Training / Knowledge

- BPC training - Medidata
- ICH E6 R2 - Inform
training - ARCO stage
- Loi Jardé - ASA score
- CTCAE - TNM
classification
- WOMAC
- Macro

Language

- French (native
language)
- English (fluent)

Computer software

- Word
- Excel
- Powerpoint
- Outlook