



F.Y.B.I

CRA

13 years of experience

Coordination, regulatory submissions, sites selection and activation, contracts set up, monitoring

PROFESSIONAL EXPERIENCE

Feb 2015 onwards, Freelance Clinical Research Associate – Study Start up activities - PM
Home based, Nice, France

- Study coordinator & monitoring: drug & medical devices documents/protocol review, contracts set up (vendors and sites), RA/EC submissions
- Cardiology (DM), nephrology (immunotherapy), urology (DM), oncology (Biotech), anesthesiology (DM), gastroenterology (No medical product study), cellular therapy (nephrology)

Jun 2009 to Dec 2014, Project Manager – pediatric specialties
Lenval Children's Hospital, Nice, France

- Project management: drug & medical devices for orthopedic surgery and pedopsychiatry : budget set up, documents redaction, EC/RA submissions, sites selection, contracts set up (vendors, sites, CRO, start up& MD companies), coordination, eTMF
- Contracts set up : clinical trials in pedopsychiatry (phase III-IV), endocrinology (phase III-IV), allergology (phase I-II-III) diabetology, oncopediatry (phase II-IV), direct contact with CRO and pharmaceutical companies

Jun 2007 to May 2009, Lead Clinical Research Associate - rare disease, hematology
National AL Amyloidosis Centre, Limoges, France, collaboration with Celgene and Inserm/CNRS
Monitoring (all visits, 30 centres) of clinical trials phase I,II,III

- Design, coordination and biostatistics for diagnostic & prognostic studies, international cooperation

Sep 2005 to May 2009, Clinical Research Associate – immunosuppressors for kidney transplantation

Nephrology department, University hospital Limoges, France, collaboration with Roche and Inserm pharmacovigilance Monitoring (all visits, 11 centres) of immunosuppressors clinical trials phase I,II,III, pharmacogenetics & economic studies industrial & institutional research

Dec 2000 to Jul 2001, Laboratory Research Engineer – Cancer immunotherapy, novel drug development

Cancer immunotherapy unit, San Rafael Scientific Institute, Milan, Italy

- “Impact of innovative dendritic cell based vaccination strategies on the clonal dynamic of tumor specific T Lymphocytes and the survival of syngeneic adenocarcinoma mouse prostate”.

QUALIFICATION/EDUCATION

- **2018 : Regular training on clinical research recommendations and law (ICH/BPC/loi Jardé, DM)**
- **2015 : Project Management Professional (PMP) certification**
Project Management Institute, USA
- **2014 : Clinical Project Manager certification**
FORMATIS, Paris, France
- **2007 : Postgraduate Degree in Methodology of Clinical Trials**
Public Health Institute, Epidemiology and Development (ISPED), Bordeaux, France
- **2004 : Clinical Research Associate certification & pharmacovigilance certification**
CLINACT, Paris, France
- **2002 : M. Sc. Degree in Biological Sciences**
Dublin City University (DCU), Dublin, Ireland

LANGUAGES

- French, Arabic, English