A.L.E.L

SENIOR CLINICAL RESEARCH ASSOCIATE

THERAPEUTIC EXPERIENCE

- **Circulatory:** Acute Coronary Syndromes (ACS) without Revascularization, Long QT-3 Syndrome
- **Endocrine/Metabolic:** Gaucher's Disease
- **Infections/Parasitic Diseases:** Hepatitis C Virus (HCV)
- **Nervous System/Sense Organs:** Alzheimer's disease, Parkinson's disease
- **Oncology:** Breast Cancer, Prostate Cancer, Non-small Cell Lung Cancer (NSCLC), Follicular Lymphoma
- **Respiratory/Infections/Parasitic Diseases/Transplants:** immunodepressed patients with influenza, hiv or Transplant Recipients

PROFESSIONAL EXPERIENCE

Sep 2016 – Present
Accelsiors, Tunisie_Sr CRA

- **Senior CRA: Non clinical activities**
- Provided input to proposals and business development. Worked on feasibility/proposal for France, Tunisia, Morocco, Algeria. Performed contact with potentials investigators conducive to patient recruitment/ participation within study milestone dates. Translated and reviewed patient tools/documents and Assisted with EC and RA submissions for Tunisia as local regulatory representative.
- Worked on Hiring process, training and mentoring new CRAs . Performed Quality Check visits.
- **Senior CRA: Clinical Research Associate on a Nephrology study**. Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimization of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues. Preparation of on-site Audit.

Avril 2015- Sep2016
PPD Paris, France_ CRAII

- **CRAII: Clinical Research Associate on a Hepatitis C Virus (HCV) study**. Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **CRAII: Clinical Research Associate on a Long QT-3 Syndrome study.** . Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **uCRA: Unblinded Clinical Research Associate on a Follicular Lymphoma study.** Performed interim monitoring visits at pharmacy. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. . Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.

2012-2014_ CRA 2011-2012_ CTA
Quintiles/ IQVIA Paris, France

- **CRA: Clinical Research Associate on an Acute Coronary Syndromes (ACS) without Revascularisation study.** Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **CRA: Clinical Research Associate on a Gaucher's Disease study.** Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **CRA: Clinical Research Associate on Alzheimer's Disease studies.** Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **CRA: Clinical Research Associate on a Parkinson's Disease study.** Performed interim monitoring visits. Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed

Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.

- **CRA: Clinical Research Associate on an immunodepressed patients with Influenza, HIV or Transplant recipients study. Performed initiation and interim monitoring visits.** Verified protocol and ICH GCP compliance. Ensured procedures were in place for appropriate optimisation of patients into the clinical study. Appointed main contact for sponsor and investigators. Reviewed CRFs and performed Source Data Verification activities. Reviewed Investigational Product storage, handling, documentation and drug accountability. Discussed corrective actions and administrative issues.
- **CTA: Clinical Trial Assistant:** Assisted CRAs on several Lupus, Circulatory and Oncology studies conducted in France and Tunisia. Assisted with IP Release activities, essential document preparation and collection. Collaborated with the SSU Lead, Local SSU and study team members. Assisted with EC and RA submissions for Tunisia. Reported study document collection statuses for IP Release to the SSU Lead. Assisted with site initiation activities, created Investigator Site Files, Pharmacy Files and SRM according to study guidelines. Reviewed study document checklists to ensure the CRA collected necessary study documents during initiation visits. Participated in initiation visit scheduling. Managed payments including investigator fees, hospital overcosts and patient reimbursements. Created invoices and transferred payments to the Accounting Department. Assisted with preparations for study closure and archiving. Performed all study administrative aspects, updated systems and maintained eTMFs. Maintained regular contact with third parties. Managed all study communication, maintained contact with sites, supported site and study team requests.

2011
Institut Claudius Regaud, Toulouse, France_Study Co-ordinator

- Participated in various Breast Cancer, Prostate Cancer and Non-small Cell Lung Cancer (NSCLC) studies. Attended hospital meetings to review patient screening activities. Ensured the ICF process was completed according to ICH/GCP. Maintained close relationships with sponsors to ensure patient statuses were regularly reported. Assisted in initiation and interim monitoring visit preparations. Followed inclusion of patients with medical staff. Maintained ICF Files. Performed Source Data Verification activities. Managed SAEs and data queries. Completed CRFs and eCRFs. Created and updated patient tracking tools. Responsible for Lab kit logistics. Responsible for collecting Patient Diaries. Followed-up with patients during scheduled visits.

LICENCES & CERTIFICATIONS

- **Completed Clinical Research Associate certified training**, Clinact Formation, France, 2011.
- **Completed Oncology Clinical Research Fundamentals certified training,** Quintiles Paris, France, 2012.
- **Completed Good Clinical Practice Barnett certified training**, Quintiles Paris, France, 2012.

PROFESSIONAL DEVELOPMENT

- Completed PPD Clinical Foundation Programme, April 2015.
- Feasibility Training, August 2015
- Site Selection Training, August 2015

- Problem solving Training, August 2015
- Leadership and management training, August 2015 and September 2018
- ICH-GCP Training, September 2018

CLINICAL TRIAL EXPERIENCE

- **Nephrology:** A phase III, randomized, double-blinded, multicenter, controlled study to evaluate the safety and efficacy of investigative study medication in patients with Anemia of Chronic Kidney Disease stage 5D.
- **Circulatory:** A phase III, multi-centre, double-blind, randomised, controlled study to evaluate the safety and efficacy of investigative study medication in patients with Acute Coronary Syndrome (ACS) without Revascularisation.
- **Circulatory:** A phase III, multi-centre, single-blind, randomised, controlled study to evaluate the safety and efficacy of investigative study medication in patients with Long QT-3 Syndrome.
- **Endocrine/Metabolic:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in children with Gaucher's Disease.
- **Infections/Parasitic Diseases:** A phase IIIb, open-label, multi-centre study to evaluate the long-term outcomes with investigative study medication with or without ribavirin in adults with Genotype 1 Chronic Hepatitis C Virus (HCV) infection.
- **Nervous System/Sense Organs:** A phase IIb, randomised, double-blind, multi-centre, parallel-group, active and placebo-controlled study of the safety and efficacy of investigative study medication in patients with Alzheimer's Disease.
- **Nervous System/Sense Organs:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in patients with Alzheimer's Disease.
- **Nervous System/Sense Organs:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in patients with Parkinson's Disease.
- **Oncology:** A phase II, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in women with Breast Cancer.
- **Oncology:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in women with Breast Cancer.
- **Oncology:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in patient with Non-small Cell Lung Cancer (NSCLC).Oncology: A phase I, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in men with Prostate Cancer.
- **Respiratory/Infections/Parasitic Diseases/Transplants:** A phase III, randomised, double-blind, multi-centre, parallel-group, active study of the safety and efficacy of investigative study medication in immunodepressed patients with Influenza, HIV or transplant recipients.
- **Oncology:** A phase III, randomised, controlled, double-blind study to compare the efficacy, safety and pharmacokinetics of investigative study medication in patients with previously untreated, advanced stage, Follicular Lymphoma.

AUDIT EXPERIENCE

- Investigator Site Audit (Site and Pharmacy)
- Clinical Supplies Facilities Audit
- Study File Audit
- Study Document Reviews/Audit
- CAPA management

COMPUTER EXPERIENCE

- MS Word, MS Excel, MS PowerPoint, MS Access, Lotus 123, Lotus Notes, CTMS, EDC, Electronic Patient Diaries, eTMF

LANGUAGES

- French: Native language
- English: Advanced
- Arabic: Proficient