

PROFESSIONAL EXPERIENCE

Senior Clinical Research Associate , PRA, Mechelen (Contractor)	Feb '16 - Aug '16
Project Manager , The Clinical Company/Vascular Research Network, Gent, B	May '15 - Feb '16
Acting Clinical Team Manager/Senior CRA , PRA, Mechelen, B	May '14 - May '15
Senior Clinical Research Associate , PRA, Mechelen and Utrecht, B and NL	Feb '11 - May '14
Clinical Research Associate , Parexel, Amsterdam, NL	May '08 - Feb '11
Clinical Research Associate , Theradex (Europe) Ltd, Crawley, UK	Oct '07 - May '08
Vaccination Nurse , Travel Clinic, Rotterdam, NL	May '07 - Oct '07
Junior Researcher , Erasmus MC, Rotterdam, NL	Apr '06 - May '07
Junior Researcher (internship), Harvard Medical School/CHB, Boston, USA	Feb '05 - Sep '05
Junior Researcher (internship), Angiogenesis Lab, Maastricht, NL	Oct '04 - Feb '05
Licensed Nurse , Home Care Service G. Hajduk, Hamm, G	May '04 - Jan '05
Book reviewer (Medicine, Psychology and Islam), NBD/Biblion, NL	Aug '03 - Jan '11
Nurse (Neurosurgery/ Neurology), University Hospital, Maastricht, NL	Sep '00 - Jan '02

Summary of Activities (Current role)

- Acting as primary contact to the sponsor
- Responsible for project budget: proper estimation resources and budget
- Manage team members and evaluation of team members performance
- Responsible for compliance to company and sponsor SOPs at project level
- Delegation of trial specific tasks to team members
- Leading team meetings and client meetings
- Escalation of issues to team members, functional managers of team members and the client
- Providing feedback to the client with regards to project metrics, project and client deliverables

Study Involvement

Oncology:

- Phase I: Multiple solid tumors
- Phase II: SCLC
- Phase II: Bladder
- Phase II: Pancreatic adenocarcinoma
- Phase II: Cervical carcinoma
- Phase III: Ovarian
- Phase III: Melanoma

- Phase III: Prostate
- Phase III: Soft tissue sarcomas
- Phase III: Glioblastoma multiforme (2 trials)
- Phase III: Brain metastases
- Phase III: NSCLC
- Phase III: GvHD (tumor immunology)
- Phase III: NSCLC (2 trials)

Hematology:

- Phase II: Myelodysplastic Syndrome - MDS
- Phase III: Myelofibrosis
- Phase III: Multiple Myeloma

Cardiology:

- Phase III: Pulmonary hypertension
- Phase III: Hypertriglyceridemia
- Phase III: Cardio vascular events
- Phase IIIb: Acute Heart Failure

Metabolic:

- Phase II: Obesity

CNS/Anesthesiology:

- Phase III: Pain

Respiratory:

- Phase III: Asthma

All studies were conducted at hospitals in Belgium, The Netherlands, France, UK and Germany.

EDUCATION

2006-2007 Master: Nursing Science
University of Maastricht (NL)

2005-2006 Master: Biological Health Science
University of Maastricht (NL)

2001-2005 Bachelor: Health Science
University of Maastricht (NL)

1997-2000 Nursing School
VTI Hasselt (B)

1990-1997 Secondary School
H-Graf Instituut Bilzen (B)

Training in Clinical Research:

- ICH-GCP, country-specific clinical trial directives and legislation
- Oncology Orientation training: oncogenesis, TNM, RECIST, CTC-AE etc.
- General Clinical Trial Procedures: ICFs, confidentiality and professionalism; Investigational Product accountability and Pharmacy visits; Pharmacokinetic-, Pharmacodynamic- and Translational- sample inspection; Regulatory documents; handling site non-compliance; visit preparation; report writing; SAE completion, reporting and reconciliation
- Study-specific Protocol and CRF completion

Licenses, Certifications & Affiliations:

- Licensed Nurse, Dutch License Number: 9053792030
- Laboratory Safety in Research, Children's Hospital Boston
- Biomedical Research Techniques V, Erasmus Postgraduate School Molecular Medicine
- Art 9: certified for animal lab test execution, Maastricht University
- Safety Microbiology Techniques, University Maastricht

SKILLS

Languages:

Dutch	Native
English	Fluent
German	Fluent
French	Moderate

Computer Skills:

Word, Excel, PowerPoint, Outlook, Electronic Data Management Systems

Other skills:

- Central ECG & BP Monitoring: ERT
- Central imaging Services: Centrallab SA, Perceptive
- Central Lab Services: Covance, ICON, Esoterix, BARC, Quintiles, CentraLabs Clinical Research
- EDC/eDiary/e-PRO: Datalabs, PHT Corporation, Medidata RAVE, INVIVODATA, RDC, Oracle InForm
- IXRS: ClinPhone IVRS, Almac, Fisher Clinical Services, Clintec, Oracle (Phase Forward)
- Clinical Trial Management Systems: Siebel Clinical (CTMS)
- PK: Esoterix
- Country experience (monitoring): France, UK, Belgium, The Netherlands and Germany.

Scientific publications:

Sebestyén Z, Schooten E, Sals T, Zaldivar I, San José E, Alarcón B, Bobisse S, Rosato A, Szöllosi J, Gratama JW, Willemsen RA, Debets R., "Human TCR that incorporate CD3zeta induce highly preferred pairing between TCRalpha and beta chains following gene transfer". J Immunol. 180(11)., June 2008

PERSONAL INFORMATION

Nationality: Belgian
Gender: Female
Date of birth: 26 Dec 1978

References available on request