Elomedic AB
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Åsa Zöchling,

Senior CLINICAL RESEARCH ASSOCIATE II
STOCKHOLM, SWEDEN

I am Senior Clinical Research Associate II with 25 years of experience as CRA, 1 year experience as unblinded CRA, 1 year experience as RSM, 1 year experience as Clinical Trial Administrator and 5 years of experience as Assistant nurse. I have worked on more than 30 Clinical trials in different Therapeutic areas: Cardiovascular, Endocrine/Metabolic, Musculoskeletal, Nervous system, Mental disorders, Rare genetic disease disorders and Oncology. I have significant experience in Cardiology, Device studies Diabetes Mellitus type 2, Hyperlipidemia, Epilepsy, Migraine, Multiple Sclerosis, Chronic Pain, Adrenal Insufficiency, Alzheimer, Osteoporosis, HIV, Amyloidosis and Duchenne's Muscular Dystrophy as SCRA. I maintain experience in Clinical trials phases I-IV in both adult and pediatric population. I have performed all types of Monitoring Visits: PSV, SIV, IMV and COV and used different Clinical and/or client specific systems for trial management, such as EDC, Medidata Rave, Paper CRF, CTMS, Impact Harmony, Veeva vault, IVRS, IWRS, eDiaries. Performed 100% or reduced SDV, on-site and remote visits.

Therapeutic and industry summary

Therapeutic Units & Indications (yrs)	• **Hematology/Oncology:** Haemophilia (1yr), Vertebrae cancer (3yrs) • **Cardiovascular, Metabolic and Critical Care:** Cardiovascular Device (6yrs), Heart valves (3yrs), Hypertension (5yrs), Hyperlipidemia (5yrs), Diabetes Mellitus type II (4yrs), Metabolic disorder (2yrs) • **Neuroscience:** Epilepsy (8yrs), Alzheimer´s disease (1yrs), Multiple Sclerosis (2yrs), Chronic pain (2yrs), Depression (2yrs), Migraine (2yrs) •**General Medicine:** Amyloidosis (2yrs), Duchenne's muscular dystrophy (1yr), Osteoporosis (2yrs) •**Infectionus and Respiratory diseases:** HIV (2yrs)
Study Phases	• PH I, II, III, IV, observational, registry, multicenter, randomized, double-blind, open-label
Patient Populations	• Pediatrics, Adult
Global/Regional Scope	• Europe (Sweden, Norway, Denmark and Belgium)

Åsa Zöchling

Senior CLINICAL RESEARCH ASSOCIATE II

Stockholm, Sweden

EDUCATION

- Vallentuna gymnasium, Vallentuna, Sweden

  English business receptionist, Dec 1999

- Gubbängens vårdgymnasium, Gubbängen, Sweden

  AN, Assistant Nurse, Jun 1994

licenSes & certificates

- Certified ESI Project Leader, August 2012
- Registered Assistance Nurse, June 1994

PROFESSIONAL EXPERIENCE

linical, stockholm, sweden

- *Senior CRA II, 2023-present*

2 phase IV, multicenter, randomized, double-blind, placebo-controlled, Nervous system (Migraine) studies in adults. Performed 19 on-site site initiations and ongoing interim monitoring. Performed 100% SDV in accordance with Monitoring plan. Use IVRS for IP set-up, accountability and management and in-house local CTMS system Veeva for reporting. Review on-site Investigator files regularly and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support.

freelance, STOCKHOLM, SWEDEN

- *Senior CRA II, 2022-2023*

The key to performing high quality results is to initially as a CRA make sure to connect and build trust with the site followed by close collaboration with sponsor and site throughout the study. As a CRA I am offering qualified support in performing all sorts of trial related activities in accordance with GCP and applicable laws and regulations.

Labcorp, STOCKHOLM, SWEDEN

- *Senior CRA II, 2021-2022*

4 phase II-IV, registry, multicenter, randomized, double-blind, open-label, Oncology (Prostate Cancer, Lymphoma Cancer) studies in adult population. Performed recruitment visits, on-site initiation visits, interim monitoring visits. Performed 100% and reduced SDV with a risk-based approach using the AIM methodology. Supported in interim analysis and database lock. Used IVRS for IP set-up, accountability and management. Reviewed on-site Investigator site files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended Investigators Meetings.

PPD, Stockholm, Sweden

- *Senior CRA II, 2018 – 2021*

8 phase I-IV, observational, registry, multicenter, randomized, double-blind, open-label, Endocrinology/Metabolic Diseases (Metabolic Disorder), Rare/Genetic Diseases/Disorders (Amyloidosis – Ph I, Duchenne's Muscular Dystrophy), Infectious/Parasitic diseases (HIV) and Nervous system (Alzheimer´s disease, Multiple Sclerosis) studies in adult and pediatric population. Performed on-site and remote site initiation, interim monitoring and close-out visits. Performed 100% and reduced SDV with a risk-based approach also using the AIM methodology. Supported in interim analysis and database lock. Used IVRS for IP set-up, accountability and management and in-house local CTMS system for reporting. Reviewed on-site Investigator files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended Investigator Meetings.

Parexel AB, Stockholm, Sweden

- *Senior CRA II, 2012 - 2018*

7 phase III-IV, observational, registry, multicenter, randomized, double-blind, open-label, Endocrinology/Metabolic Diseases (Diabetes Mellitus Type II), Rare/Genetic Diseases/Disorders (Hemophilia), Nervous system (Multiple Sclerosis, Epilepsy) studies in adult population. Performed on-site and remote site initiation, interim monitoring and close-out visits in Sweden, Norway and Denmark. Performed 100% and reduced SDV with a risk-based approach. Supported in interim analysis and database lock. Used IVRS for IP set-up, accountability and management and inhouse local IMPACT system for reporting. Reviewed on-site Investigator files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training

and query resolution support. Attended Investigator Meetings. Attended one on-site audit. Had a role as a mentor for new CRA´s and conducted assessment visits.

St. jude medical, veddesta, Sweden

- *Senior CRA I, 2009 - 2012*

20 phase III-IV, observational, registry, multicenter, randomized, double-blind, open-label, Medical Device (Cardiovascular Device, Heart valves), Nervous system (Chronic Pain, Depression) studies in adult population. Performed on-site initiation, interim monitoring and close-out visits in Sweden, Norway and Finland. Performed 100% SDV. Supported in interim analyses and database lock. Used local house system for reporting. Reviewed on-site Investigator files and ensured safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended and organized Investigator Meetings and trainings. Assisted with submission to the ethics committees and the authorities. Local project management in Scandinavia (Sweden, Norway and Denmark) including mentoring personnel.

Trial Form Support, Stockholm, Sweden

- *Senior CRA, 2008 – 2009*

2 phase III, multicenter, randomized, double-blind, Endocrinology/Metabolic Diseases (Diabetes Mellitus type II) studies in adult population. Performed on-site and remote site initiation, interim monitoring and close-out visits. Performed 100% SDV. Supported in interim analysis and database lock. Used IVRS for IP set-up, accountability and management and in-house local system for reporting. Reviewed on-site Investigator files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended Investigator Meetings.

DOCS International, Stockholm, Sweden

- *Senior CRA, 2005 – 2008*

2 phase III, registry, multicenter, randomized, open-label, Hematology/Oncology (Vertebrae cancer), Musculoskeletal (Osteoporosis) studies in adult population. Performed on-site initiation, interim monitoring and close-out visits. Performed 100% SDV. Supported in interim analysis and database lock. Used local system for reporting. Reviewed on-site Investigator files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended Investigator Meetings. Performed submission to the ethics committees and authorities. Responsible for training of new CRA´s. Local project management for Sweden.

Pfizer, täby, Sweden

- *CRA, 2001 – 2005*

2 phase III-IV, multicenter, randomized, double-blind, Cardiology/Vascular Diseases (Hypertension), Endocrinology/Metabolic Diseases (Hyperlipidemia) studies in adult population. Performed on-site site initiation, interim monitoring and close-out visits. Performed 100% SDV. Supported in interim analysis and database lock (paper CRF used). Reviewed on-site Investigator files and ensured subject safety by overseeing timely and accurate AE/SAE reporting and follow-up. Maintained regular site staff contact, training and query resolution support. Attended Investigator Meetings.

covance, danderyd, Sweden

- *Clinical project administrator, 1999 – 2000*

Responsible for all study documentation and other administrative tasks linked to the studies. Support function to the CRA´s. Responsible for all facilities contract negotiations and for the reception.

danderyds hospital, danderyd, Sweden

- *Assistant nurse, 1994 – 1999*

Regular duties performed on Orthopedic ward and Palliative Care (Cancer patients).

PROFESSIONAL Development

- PPD Clinical Foundation Program
- Certified CSSR-S Scale monitor, Stockholm, Sweden
- Trained to perform clinical ECG and research ECG recordings, Stockholm, Sweden
- Trained in therapeutic areas in the studies I have been involved in by attending lectures, congresses, internal meetings
- General introduction to Oncology (Breast cancer and Lung cancer), Danderyd, Sweden
- Course in project management, ESI International, Stockholm, Sweden
- Course in cooperative agreements between the Medtech industries and customers, Swedish Medtech, Stockkholm, Sweden
- Basic course in Clinical Trials, Swedish Academy of Pharmaceutical Sciences, Stockholm, Sweden
- Cardicac surgery fundamental certification, Leiden University Medical Center, Leiden, Netherlands
- ICD, Pacemaker, Biological and mechanical Heart valves course, SJM, Zaventem, Brussels
- Course in clinical trials performed on Medical devices, Swedish Academy of Pharmaceutical science, Stockholm, Sweden

PROFESSIONAL affiliations

- Member of the Swedish Association of Pharmaceutical Science

Languages

Native Tongue: Swedish

Proficient: English, Norwegian, Danish

REgulatory Experience

- Regulatory submission experience for Sweden both for Pharma and for Medical devices.

Therapeutic Experience and Expertise

- Nervous system: Multiple Sclerosis, Epilepsy, Alzheimer's Disease, Chronic Pain, Migraine
- Hematology/Oncology: Hemophilia, Vertebrae Cancer
- Endocrinology/Metabolic Diseases: Diabetes Mellitus Type II, Metabolic Disorder, Hyperlipidemia
- Cardiology/Vascular Diseases: Hypertension
- Device: Cardiovascular Device, Heart valves
- Musculoskeletal: Osteoporosis
- Infectious/Parasitic Diseases: HIV
- Psychiatry/Psychology/Mental Disorders: Depression
- Rare/Genetic Diseases/Disorders: Amyloidosis (Ph I), Duchenne's Muscular Dystrophy

Scale/patient Reported outcome measures experience

- Mini-Mental State Examination (MMSE)
- European Quality of Life Group´s EQ-5D
- C-SSRS
- MSQ
- MQoL
- MIBS
- SF-36
- HADS

Audit Experience

- Investigator Site Audit by CRO. Role in audit – CRA.
- Investigator Site Audit by Sponsor. Role in audit – CRA.

Computer Experience

- MS Office (Word, Excel, Powerpoint)
- CTMS, eTMF (Veeva Vault), IMPACT HARMONY, Sharepoint
- EDC (Inform, Medidata RAVE)
- eDiaries