



**AKADEMISKA
SJUKHUSET**

National competency documents for CRNs in Sweden

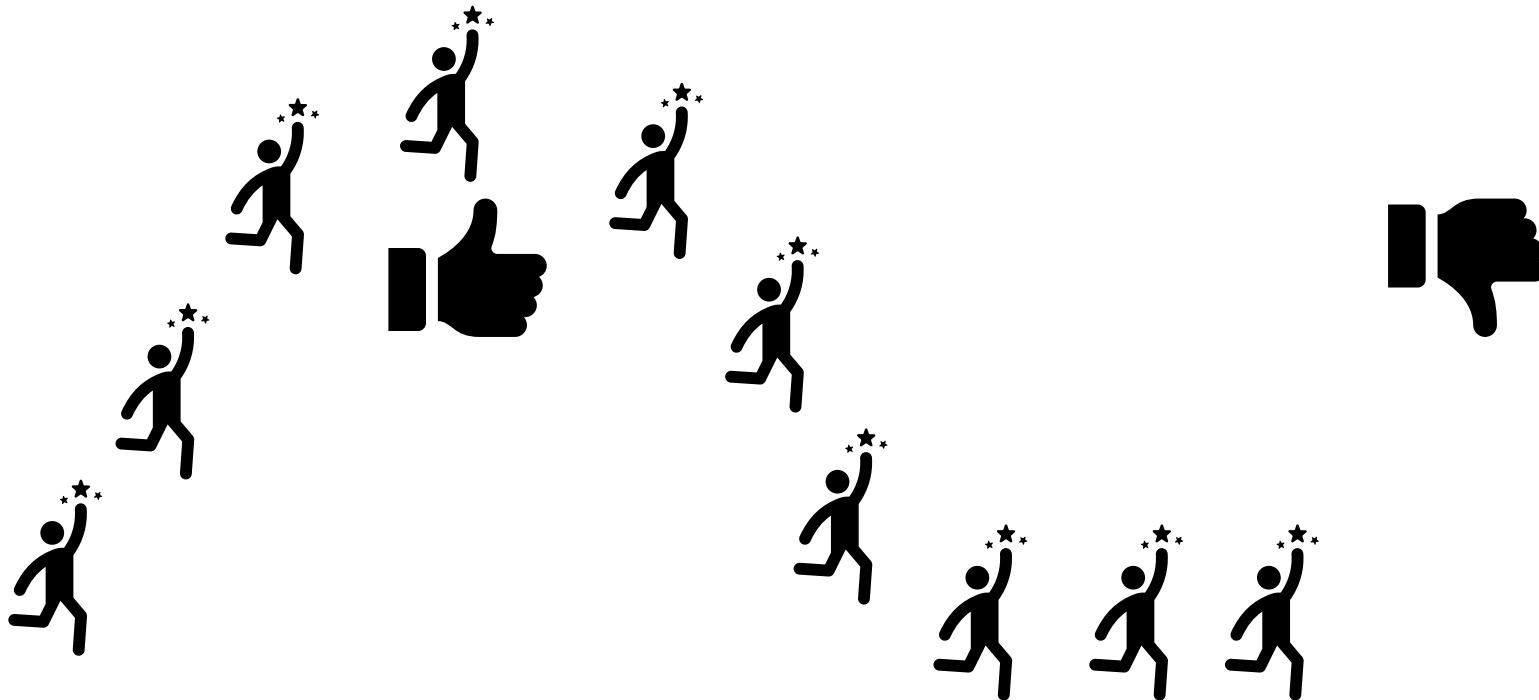
Sabine Lindén, RN MSc

R&D department, Uppsala University Hospital, Sweden

QUESTION

Has someone asked you this question before:

You are a CRN? What does a research nurse do?



There is no real change without people who dare to think in new dimensions...

Local CRN group

68 semi-standardised interviews and workshops with 55 CRNs to delineate CRN role



2018

2019 / 2020



Introductory year (12 months)

Newly hired CRNs. We offer GCP certificate, course handling of blood samples, webinars, introductory day with guest speakers, Clinical guidance and reflection groups, a mentors program and support from the local CRN network



National network

Embedded into the Swedish Pharmaceutical Society which is a non-profit organization for professionals engaged in the field of Pharmaceuticals. Member fee 45 Euro/year.

National conference

Aim is to get together, educate and inspire CRNs and midwives from all around Sweden.

Local competency model for CRNs

Evaluate interviews and started a project group in cooperation with HR department. Started several project groups to work with routines, SOPs, guidelines and checklists under 2019.



2019

2020

National job description for CRNs

National project group with members from all seven university hospitals in Sweden. Research grant reimbursed meeting hours for participants. Jobb description published as open source document. Possible to change / edit document regarding specific job position and competency level.



2022

National project group

Continued work with results from the national jobb description project. Started to define competencies, educational requirements and specialized practice. The project group has 17 members and includes a nursing researcher.



A conference for CRNs and midwives is emerging...

Local CRN conference

Workshops with 55 CRNs and midwives to deliniate CRN role – founding work for the local competency model



2018

Virtual conference

The planned in person conference needed to be changed to a virtual conference due to Covid pandemic. About 130 participants, without attendance fee.



2020

National conference

In cooperation with Lif who is the industry organization for research-based pharmaceutical companies in Sweden. 159 in person attendees, 50 speakers and contributors and 110 virtual participants.



2022

Regional CRN conference

Workshops with about 100 CRNs from our region (mid Sweden), guest speaker from England



2019

First national conference



2021

First in person and virtual conferecnce in Sweden. Exhibition area and interview with sponsors during conference day. Hybrid event with 90 in person attendees, 50 speakers and representatives and about 130 virtual participants.
www.vikanforskning.se

National conference

Planned as a cooperation project with Lif (industry organization for research-based pharmaceutical companies in Sweden), Uppsala Research Center (public CRMO) and Biobank Sweden. Need for sponsors and collaborations.

2023



How everything started...



2018

A project group with 8 senior CRNs started to work with a local competency model and introductory program for inexperienced CRNs at the Uppsala University Hospital.

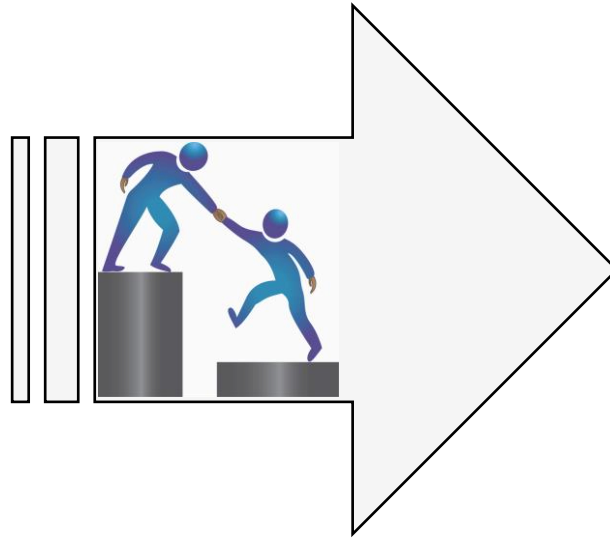
Local competency model at the Uppsala University Hospital

Competency model goals:

- professional development
- job satisfaction
- job continuity



12-months introductory program



- GCP course
- Course handling of blood samples
- Webinars
- Introductory day with guest speakers
- Clinical guidance (12months)
- Reflection groups (every 4weeks)
- Mentors program
- Support from local CRN network

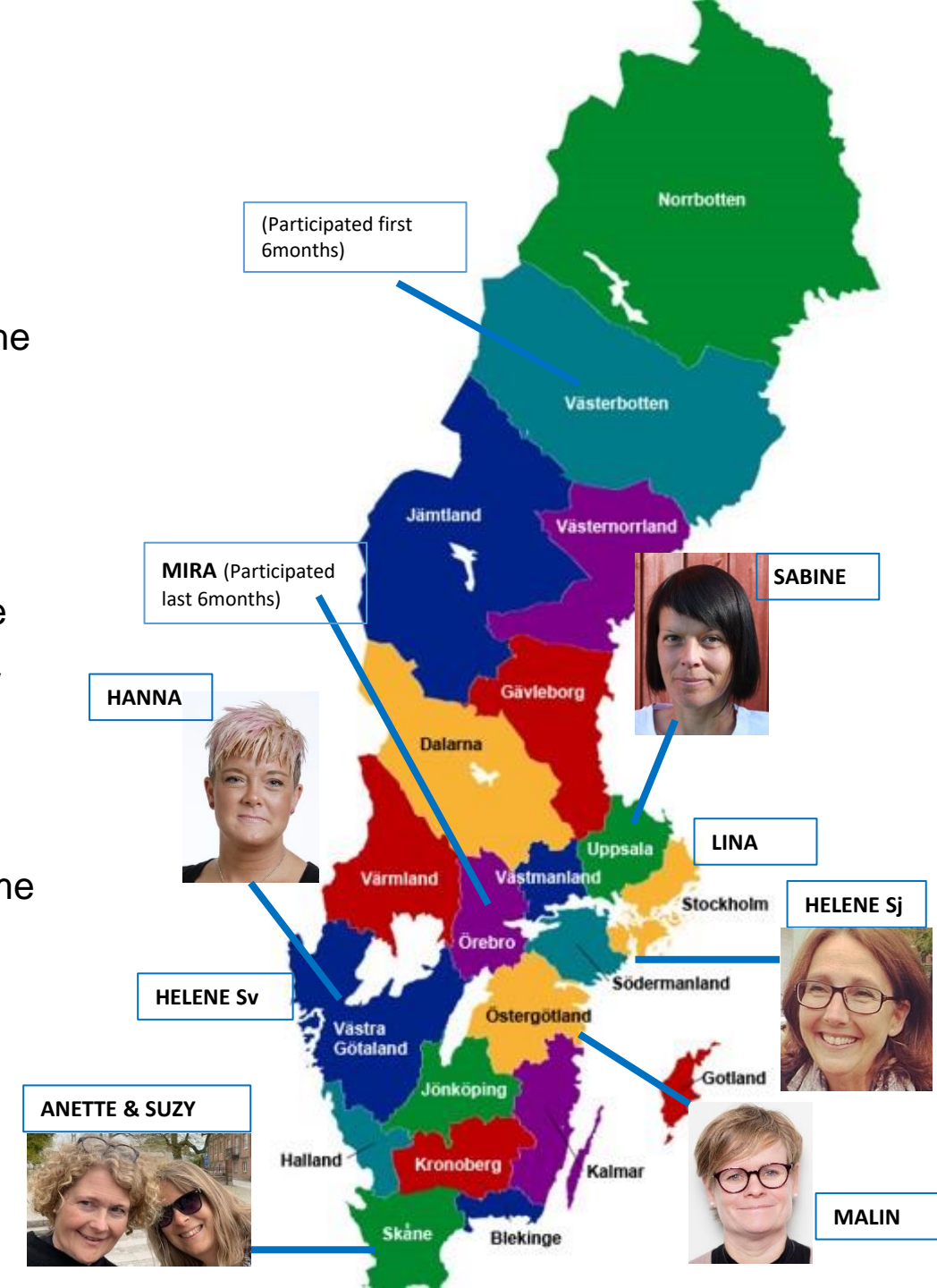


Marie, CRN

Our way to a national job description...

- 1) Presented our local competency model for other research facilities at the regional CRN conference in 2019
- 2) Had in-person meetings with key players / leaders at research facilities
- 3) Got attention nationally and support from industry / organizations
- 4) Got research funding for our project group. We could offer to reimburse meeting hours for participants (up to two participants from each university hospital in Sweden)
- 5) Started the project with an in person meeting / kick-off
 - Schedule for digital meetings and plan project meeting dates a long time in advance!
- 6) We had reference groups and sent out draft versions to referral

Total time frame for the project: 1.5 years, 15 virtual meetings



National job description document structure



General qualifications and knowledge

- RN certificate / license
- actual GCP certificate
- competency / knowledge about legal background and ethical issues



Before the study starts

- CRN/midwife responsibilities
- Investigator delegates to CRN
- Sponsor delegates to investigator / CRN



During an ongoing study



Study closure / end of clinical project

What we learned during the project...

- Engage chief nurses and National Board of Nursing
- Send out draft document to a lot of key players for referral
- Be flexible with meeting dates and hours because of other commitments who interfere with scheduled meetings
- As a project lead – be aware of a lot of administrative work load in between the meetings
- A great way to revise a document is to use Office365 Sharepoint, “comment function”
- Revise the document in “online” mode (updates the draft version automatically)
- Make sure that ALL members work with the same document version!

Work in progress....

In January 2022 we started a new national working group with expert guidance from a nursing researcher and lecturer.

Goal is to establish a

national competency model for CRNs and midwives in Sweden

We are trying to define the roles and practice domains of the CRN. We try to focus on the clinical practice domain because this could lead to a CRN specialty practice education.

provide direct nursing care
to research patients

activities to support protocol
implementation

record research data in medical record
and approved case report form

Monitor the research patient and report
potential AE

Coordinate and facilitate communication
among research sites and team members

provide teaching to research
patients and family

Assure data collection based
on study endpoints

Research participant recruitment

Provide nursing expertise

Screening potential research
participants for eligibility

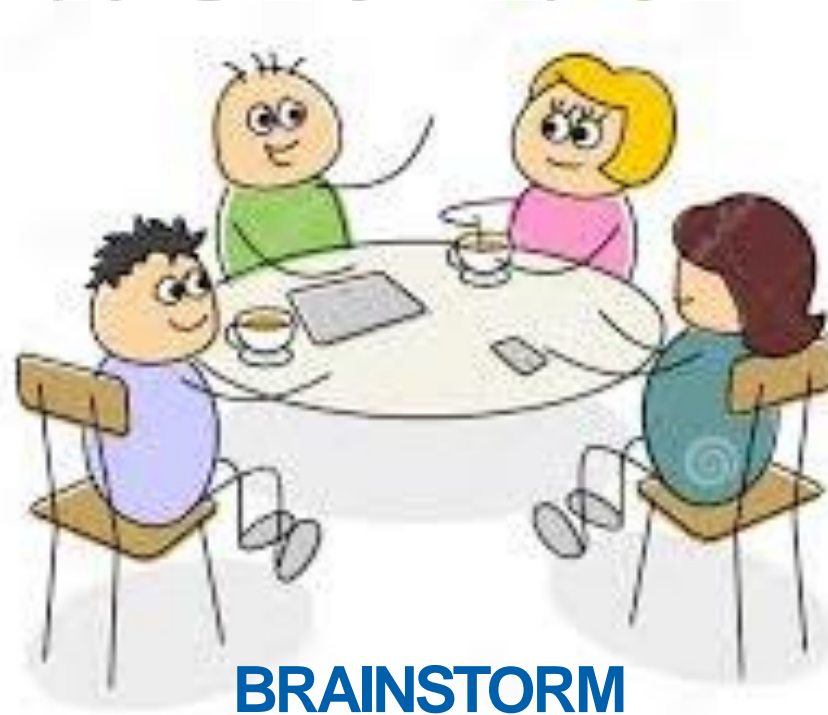
Participate in site visits and audits

Collaborate with the interdisciplinary team

human subject protection during
informed consent process

facilitate processing and handling of
research specimen and material

facilitate scheduling and coordination of
study procedures



CRN 2010 Domain of Practice Committee 2009.
“Building the Foundation for Clinical Research
Nursing: Domain of Practice for the Specialty of
Clinical Research Nursing”

- Clinical Practice
- Human Subject Protection
- Contributing to the science
- Care coordination and continuity
- Study management

Sherwood & Barnsteiner (2013) “Quality and
Safety in Nursing: A Competency Approach to
Improving Outcomes”

- ❖ Patient-Centered Care
- ❖ Teamwork and Collaboration
- ❖ Quality Improvement
- ❖ Evidence - Based Practice
- ❖ Safety
- ❖ Informatics

Preliminary document structure



Background information such as:

- care vs research,
- ICH-GCP and other legal requirements,
- patient vs research participant,
- Scope of practice and populations served by CRNs/midwives
- New trends and area of practice



CRN role definition vs other roles in a multi professional research setting



Scope and standards of practice

Further work is needed... (wish list)

- National introductory program (online)
- Include more primary care facilities into the national network
- Literature on clinical research nursing, scope and standards of practice, core curriculum
- Clinical research nursing lectures in nursing school
- Internship possibilities and student placement
- Specialized CRN/midwife nursing program which is recognized by the National board of nursing and the ministry of health
- Possibility for a masters and PhD program in clinical research nursing/midwifery





**Wanna know more?
Get in contact with us!**



Sabine.linden@akademiska.se

Reference and link list

- Backman Lönn** B.; Hajdarevic S.; Olofsson N.; Hörnsten, Å.; Styrke J. (2022) "Clarifying the role of clinical research nurses working in Sweden, using the Clinical Trial Nursing Questionnaire – Swedish version". Online: [Clarifying the role of clinical research nurses working in Sweden, using the Clinical Trial Nursing Questionnaire – Swedish version \(wiley.com\)](https://onlinelibrary.wiley.com/doi/10.1111/crn.12555)
- Barlow** C & Farrar H.M. (2013) "The role of the clinical trial nurse in Oklahoma", Oklahoma Nurses 58 (2): p4
- Bevans** M & Hastings C; Wehrle L; Cusack G; Matlock A.M.; Miller-Davis C; Tondreau L; Walsh D; Wallen G.R. (2011) "Defining Clinical Research Nursing Practice: Results of a Role Delineation Study", Clinical and Translational Science 2011 Dec 4 (6): 421-427
- Brinkman-Denney** S (2013) "An international comparison of the clinical trials nurse role", Nursing management 20 (8): 32-40
- Castro** K; Bevans M; Miller-Davis C; Cusack G; Loscalzo F; Matlock A.M.; Mayberry H; Tondreau L; Walsh D; Hastings C (2011) "Validating the Clinical Research Nursing Domain of Practice", Oncology nursing Forum March 38 (2) E72-E80
- Catania** G; Poiré I; Bernardi M (2012) "The role of the clinical trial nurse in Italy", European journal of oncology nursing 16 (1) 87-93
- Hastings** C. (2010) National Institute of Health Clinical Center, Nursing and patient care service. "CRN 2010 Domain of Practice Committee 2009. Building the Foundation for Clinical Research nursing: Domain of Practice for the Speciality of Clinical Research Nursing 2009" Online: http://www.cc.nih.gov/nursing/crn/DOP_document.pdf
- Hastings** C; Fisher C.A.; McCabe M.A. (2012) "Clinical Research nursing: A critical resource in the national research enterprise", Nursing Outlook 2012 May 60 (3): 149-156
- Hill** G and MacArthur J (2006) Professional issues associated with the role of the research nurse. Nursing Standard 20(39): 41–47
- Poston** R.D. & Buescher C.R (2010) "The Essential Role of the Clinical Research Nurse (CRN)", Urologic Nursing 30 (1): 55-77
- Purdum** M.A. Petersen S; Haas B.K. (2017) "Results of an Oncology Clinical Trial nurse Role Delineation Study", Oncology Nursing Forum 44 (5): 589-595
- Sadler** G.R.; Lantz J.M.; Fullerton J.T.; Dault Y. (1999) "Nurses' unique roles in randomized clinical trials" Journal of professional nursing 15 (2): 106-115