

Inspirace ze zahraničí

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Cíl příspěvku



- **Definovat pojmenování a kompetence jednotlivých členů týmu v klinickém hodnocení léčiv**
- **Metodika: dohledávání v zahraničních odborných profesních časopisech, dokumentech, zákonech, studijních programech, profesních webech**
- **Omezení: - kvantum informací pro zpracování
; - Jazyková dostupnost – informace převážně z anglicky mluvících zemí**

Kdo je kdo?

- **Sestra v klinickém hodnocení léčiv?**

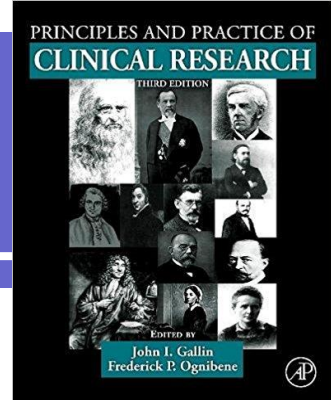
- Vzdělání a kompetence dané zákonem

- **Studiový koordinátor??**

Ve většině zemí sestra, může to být i jiný pracovník

- **Data manager???**

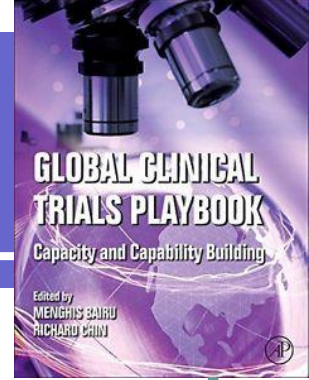
Data manager (správce dat)



Pohled č. 1 – ojedinělý

- Výhradní odpovědnost data managera – **je sbírání a dokumentování dat.**
- Abstrahuje data ze zdrojových dokumentů a vkládá je do výzkumných formulářů
- Provádí kontroly kvality údajů, nesrovnalosti a chybějící data hlásí PI nebo ostatním členům týmu.
- Sleduje nárůst počtů pacientů ve studii

Data manager (správce dat)



Pohled 2 – většinový pohled, pracovní nabídky

- Uchovává specifikace ověřování dat (pro automatizované a ruční kontroly)
- Vytváří a udržuje zprávy o stavu studie pro sledování dokončení CRF / eCRF a řízení nesrovnalostí. Sleduje integritu, kvalitu a validitu dat. Aktualizuje studiovou databázi.
- Komunikuje s koncovými centry, ověřuje správnost dat.

Jeho komunikace v eCRF je označena jako DM

Clinical research associate (CSA)

- **Volný překlad: klinický výzkumný pracovník / spolupracovník**
- **Často používaný termín – sbírá data ze zdrojové dokumentace a přenáší je do elektronických formulářů, dohledává a řeší nesrovnalosti ve zdrojové dokumentaci – není to sestra ani lékař**

Sestra v klinickém hodnocení léčiv

Klinické hodnocení léčiv je v anglickém originále nazváno Clinical trials, proto sestry pracující v klinickém hodnocení jsou v zahraničí nazývány:

Clinical trial nurse (CTN),

Clinical trial co-ordinator (CRC),

Study site co-ordinator (SSC),

Study co-ordinator (CS) (Van Doren, 2018)

Clinical research nurse (CRN) (Gallin, Ognibene, 2017)

Velká Británie

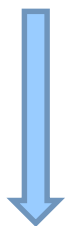


- **Harmonizace zákona s GSP v r. 2004**
↓
- **Vznik „National Institute for Health Research (NIHR)”**
↓
- **Vytvoření standardů pro sestry v klinickém hodnocení léčiv. Definování role sestry v clinical trials, množství publikací v této oblasti.**
↓ ↓
- **Účel standardů: bezpečnost pacienta a bezpečnost sestry, která poskytuje péči pacientovi v klinickém hodnocení**

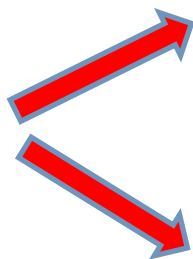
Velká Británie – pojmenování sestry



Clinical trial nurse (CTN)
nebo **Clinical trial reseach Nurse**



dvojrole:



1. přímá péče o pacienta

2. koordinátor klinické studie

V Británii sestra = study co-ordinator (Green, L.)



Možnosti vzdělání v clinical trials GB

**Magisterské studium v clinical trials:
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Univ. of Glasgow, Univ. of Sheffield...**

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Our programme is delivered and assessed completely online through our virtual learning environment with access to a wide range of

- Programy navazují na Bc. studium,
- určeno pro sestry, porodní asistentky a příbuzné zdravotnické obory.

Austrálie



Pojmenování pro sestru v klinickém výzkumu:
Clinical trial nurse (CTN) nebo **Clinical research Nurse**
nebo **Research co-ordinator**

Problém se zaměstnáním a prestiží těchto sester.
Sestra, která pracuje u lůžka má vyšší platební
ohodnocení a prestiž než sestra ve výzkumu.

Možnost vzdělání v oblasti Clinical trials –
magisterské studium např. na univerzitě v Sidney
Master of Clinical Trials Practice

Nizozemsko



- **Vlastní název pro výzkumní sestru v klinickém hodnocení:**
- **Onderzoeksverpleegkundige**
- **Velké množství nestátních společností zajišťujících klinické hodnocení léčiv v domácím prostředí**
- **Samostatný studijní program pro clinical trials nedohledán**

USA

- **National Institutes of Health Clinical Center Nursing and Patient Care Services**
- **Clinical research Nursing model of Care - přesně definuje roly sestry v klinickém výzkumu – přesně definuje role sestry.**
- **Možnost magisterského studia na řadě univerzit, clinical trials je součástí vzdělávání, ne samostatným studijním oborem**

Role sestry v klinickém výzkumu



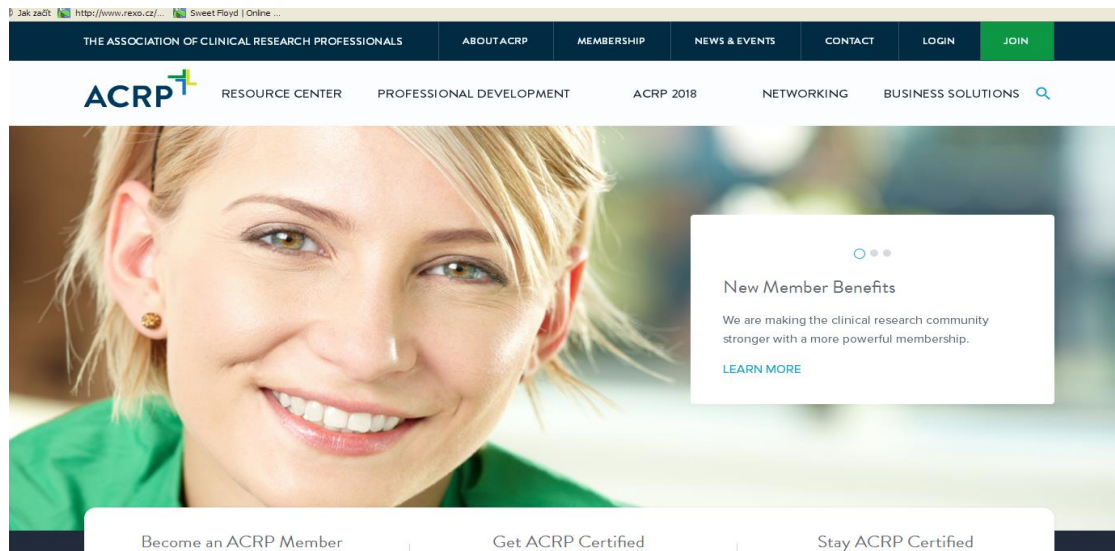
National Institutes of Health Clinical Center
Nursing and Patient Care Services

Appendix 2 – Clinical Research Nursing - Roles in the Care Delivery Model

Scope of Activity	Protocol Coordinator Role	Primary CRN Role	Assigned CRN Role	Clinical Research Tech Role
Focus of Work	Group of participants on a given protocol	Individual participant who requires continuity for care spanning more than one day or visit	Individual participant	Individual participant or unit tasks (i.e. setting up research bloods)
Time Frame	Duration of Protocol or long term program of care	Episode of Care (inpatient admission or one or more protocol related visits)	Shift/Visit	Shift/Visit
Assessment	Overall impact of protocol, level of nursing care required, clinical needs of patient population (group assessment)	Health status, needs and responses over an episode of care – presenting and as they evolve during participation (individual assessment).	Immediate presenting needs, follow-up based on prior caregiver report, new or emerging needs based on changes in therapy or health status	Immediate needs and responses to care; participant initiated requests or concerns
Planning	Plan and standards for specific protocol-based care and patient population-based care that become part of the protocol implementation plan.	General and specific goals and plan for episode of care (to be achieved by the end of the episode	Priorities for care during shift, including delegation of appropriate activities. Review of existing plan; recommendations for changes based on shift-to-shift observations	Priorities for care during shift
Implementation	Education of staff; preparation of protocol specific forms and research participant educational materials; ongoing participation in research team coordination of care	Implementation of nursing plan of care, medical orders and protocol procedures, incorporating participant feedback and adjusting as indicated by participant response	Implementation of nursing plan of care, medical orders and protocol procedures	Implementation of delegated care per plan of care and protocol

ACRP

- **ACRP - The Association of Clinical Research Professionals** <https://www.acrpnet.org>



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- **Blogy: Are Underqualified Monitors Damaging Your Clinical Trials?**

The International Association of Clinical Research Nurses (IACRN)

<https://iacrn.org/>



The screenshot displays the IACRN website homepage. At the top left is the IACRN logo, which features a stylized sunburst behind the acronym 'IACRN' and the full name 'International Association of Clinical Research Nurses' below it. To the right of the logo, there are two orange buttons: 'CUSTOMER SERVICE' and 'CONTACT IACRN'. Below these buttons, the website's vision and mission statements are presented. The vision statement is 'Enhancing clinical research quality and safety through specialized nursing practice.' The mission statement is 'The International Association of Clinical Research Nurses is a professional nursing organization. Its purpose is to define, validate and advance clinical research nursing as a specialty practice and to support the professional development of registered nurses who directly or indirectly impact the care of clinical research participants across all clinical specialties.' A blue banner below the mission statement repeats the vision statement. A dark grey navigation bar contains links for Home, About Us (with a dropdown arrow), Membership, Marketing, Donations, Conferences, Education, News, and Discussion. On the left side, a dark grey sidebar lists several links: IACRN Board of Directors and Officers, Strategic Plan, Policies and ByLaws, Partners & Friends, Job Posting Policy and Pricing, and Contact Us (with a sub-link for Twitter). At the bottom left, there is an email subscription form with a label 'Email' and an input field. The main content area features the title 'The International Association of Clinical Research Nurses (IACRN)' in a large, bold, gold font. Below this title, the vision and mission statements are repeated. A 'Definition' section is highlighted with a blue border and contains the text: 'Clinical Research Nursing is the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol. This specialty practice incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical'.

Vision - Enhancing clinical research quality and safety through specialized nursing practice.

MISSION - The International Association of Clinical Research Nurses is a professional nursing organization. Its purpose is to define, validate and advance clinical research nursing as a specialty practice and to support the professional development of registered nurses who directly or indirectly impact the care of clinical research participants across all clinical specialties.

Enhancing clinical research quality and safety through specialized nursing practice.

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The International Association of Clinical Research Nurses (IACRN)

Vision
Enhancing clinical research quality and safety through specialized nursing practice.

Mission
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Global Research Nurse

The screenshot shows a web browser window with the address bar displaying "Sweet miya | Online ...". The website header includes the logo for "THE GLOBAL HEALTH NETWORK" with a flag icon, followed by input fields for "Email" and "Password", and a "LOG IN/REGISTER" button. A "MORE" dropdown menu is also visible. The main navigation bar features the title "Global Research Nurses" and a search bar with the placeholder text "What are you looking for?" and a "SEARCH" button. Below the navigation bar, there are several menu items: "Home", "About This Site", "Community", "Articles", "GRN Chronicles", "Research resource hub", "eLearning", and "GRN Twinning". A sub-navigation bar highlights "The Role of a Clinical Research Nurse" and includes links for "Featuring Network Participants", "Members", "Blogs", "Groups", and "Events and networking". The main content area is titled "The Role of a Clinical Research Nurse" and contains several paragraphs of text. The first paragraph discusses the focus of clinical research nursing. The second paragraph mentions a recent publication and includes a link to "details here". The third paragraph highlights competency-based standards. The fourth paragraph discusses the establishment of the CRN in the USA. The fifth paragraph mentions an alternative competency framework from WHO. On the right side, there is a sidebar with a section titled "'Role Transition' when becoming a Research Nurse" and a section titled "What is a research nurse and what do they do?".

Sweet miya | Online ...

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The Role of a Clinical Research Nurse Featuring Network Participants Members Blogs Groups Events and networking

The Role of a Clinical Research Nurse

Clinical research nursing focuses on the care of research participants and the protocols of clinical research and trials. The clinical researcher nurse (CRN) balances the needs of the participant and the requirements of research across settings. The result: exceptional, ethical, and safe care that yields reliable, valid data and findings, high quality research outcomes, and, in time, better quality health care.

A recent publication *Clinical Research Nursing: Scope and Standards of Practice* ([details here](#)) addresses advances regarding the Clinical Research Nurse specialist's unique body of knowledge: nursing care; research regulations; scientific process; and data collection, analysis, and interpretation.

This publication highlights seventeen competency-based standards of CRNs frame evaluation of practice outcomes and goals and delineate what is expected of all CRNs and the scope of practice (which establishes the who, what, where, when, why, and how of the CRN practice) is the context for applying the competency-based standards.

We believe that the establishment of the CRN as a specialist in the USA will enhance the practice and career opportunities of clinical research nurses globally.

An alternative competency frameworks for all team members, including clinical research nurses, has been formulated by the WHO. The framework can be applied to any clinical research study, regardless of the size of the team, place, disease focus and type of research. Together with its supporting tools, the framework can be used to plan staffing requirements for a study, to carry out appraisals of staff, to guide career development and to create educational curricula for research staff.

'Role Transition' when becoming a Research Nurse

Following the decision to become a research nurse, the first few months can be quite difficult and can really make you wonder whether or not you have made the right decision. You miss the routine of the ward, the camaraderie of your peers and feeling like you actually know what you are doing! [Read more](#)

What is a research nurse and what do they do?

I am often asked, by nurses not working in research, "what is a research nurse and what do they do" "what are the responsibilities of a research

