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METHODOLOGICAL STUDY

Competencies and role of the Clinical Trial Nurse in Pediatric Hemato-Oncology: proposal for a National Core Curriculum and Job Description

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Findings:

This study developed a competency framework, a national Core Curriculum, and a Job Description for Clinical Trial Nurses in pediatric hemato-oncology by integrating evidence from a systematic review and a multicenter observational study. The framework identifies seven core competency domains, translates them into observable professional responsibilities, and proposes measurable performance indicators and expected outcomes. The resulting model provides a structured reference to support education, professional development, and standardization of the Clinical Trial Nurse role in the Italian context.

ABSTRACT

BACKGROUND: clinical trials, particularly in oncology, require complex collaborative networks and multidisciplinary expertise to ensure scientific quality and participant safety. In this context, the Clinical Trial Nurse (CTN) plays a key role, especially in pediatric hemato-oncology, where clinical complexity and patient vulnerability demand highly specialized competencies. However, in Italy, there is still significant heterogeneity and a lack of shared standards regarding the CTN role, training and responsibilities.
OBJECTIVES: to define a clear and shared professional profile for the CTN in pediatric hemato-oncology by developing a national Core Curriculum and Job Description, aimed at standardizing education, competencies, evaluation and professional recognition.
METHODS: an integrated approach was adopted, combining a review of the international literature with empirical data from a multicenter AIEOP survey. The process included three phases: identification of key competencies, analysis of the national context, and development of a shared competency model and Job Description, guided by the Competency-Based Education framework.
RESULTS: a Core Curriculum structured into seven competency domains was developed: clinical, methodological, communication-relational, autonomy, critical thinking, leadership and teamwork. The Job Description outlines responsibilities, activities and observable standards, supported by performance indicators and outcomes to ensure quality of care, data integrity and patient safety.
CONCLUSIONS: formalizing the CTN role is essential to improve the quality, safety and consistency of pediatric clinical trials. The adoption of a shared national framework supports professional recognition, the development of advanced competencies and continuous improvement in research and care processes.

KEYWORDS: *Clinical Trial Nurse, Pediatric Hemato-Oncology, Competency, Core Curriculum, Job Description, Professional Role*

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STUDIO METODOLOGICO

Competenze e ruolo del Clinical Trial Nurse in Emato-Oncologia Pediatrica: proposta di Core Curriculum e Job Description Nazionale

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Riscontri:

Lo studio ha sviluppato un framework di competenze, un Core Curriculum nazionale e una Job Description per l'infermiere di ricerca in emato-oncologia pediatrica, integrando le evidenze di una revisione sistematica e di uno studio osservazionale multicentrico. Il framework identifica sette domini di competenza, li traduce in responsabilità professionali osservabili e propone indicatori di performance e outcomes misurabili. Il modello risultante costituisce un riferimento strutturato per orientare formazione, sviluppo professionale e standardizzazione del ruolo dell'infermiere di ricerca nel contesto italiano.

ABSTRACT

BACKGROUND: gli studi clinici, in particolare in oncologia, richiedono reti collaborative complesse e competenze multidisciplinari per garantire qualità scientifica e sicurezza dei partecipanti. In questo contesto, l'infermiere di ricerca clinica (CTN) rappresenta una figura chiave, soprattutto in emato-oncologia pediatrica, dove la complessità clinica e la vulnerabilità dei pazienti richiedono elevate competenze specialistiche. Tuttavia, in Italia persistono eterogeneità e mancanza di standard condivisi per ruolo, formazione e responsabilità del CTN.

OBIETTIVI: definire un profilo professionale chiaro e condiviso del CTN in emato-oncologia pediatrica, sviluppando un *Core Curriculum* nazionale e una *Job Description* per standardizzare formazione, competenze, valutazione e riconoscimento professionale.

METODI: è stato adottato un approccio integrato basato su revisione della letteratura internazionale e dati empirici derivanti da una *survey* multicentrica AIEOP. Il processo si è articolato in tre fasi: identificazione delle competenze chiave, analisi del contesto nazionale e costruzione di un modello condiviso di competenze e *Job Description*, secondo il paradigma della *Competency-Based Education*.

RISULTATI: è stato elaborato un *Core Curriculum* strutturato in sette domini di competenze: cliniche, metodologiche, comunicativo-relazionali, autonomia, pensiero critico, *leadership* e *teamworking*. La *Job Description* definisce responsabilità, attività e standard osservabili, supportati da indicatori di *performance* e da *outcomes* per garantire qualità assistenziale, integrità dei dati e sicurezza del paziente.

CONCLUSIONI: la formalizzazione del ruolo del CTN rappresenta un passo essenziale per migliorare qualità, sicurezza e omogeneità dei *trial* pediatrici. L'adozione di un modello nazionale condiviso favorisce il riconoscimento professionale, lo sviluppo di competenze avanzate e il miglioramento continuo dei processi di ricerca e assistenza.

KEYWORDS: *Clinical Trial Nurse, Pediatric Hemato-Oncology, Competency, Core Curriculum, Job Description, Professional Role*

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BACKGROUND

Clinical trials are research studies involving human participants that are designed to answer specific scientific questions through controlled experimental methods (1). Conducting clinical trials requires a broad, well-structured collaborative network that includes academic institutions, healthcare organizations, cooperative groups, governmental agencies, private companies, and non-profit organizations (2). Within this framework, oncology has emerged as one of the leading areas of clinical research over the past decades, driven by continuous scientific advances and sustained investment. Today, cancer represents the most extensively investigated disease area in clinical trials worldwide (3). This evolution has accelerated the development of innovative therapeutic strategies to identify effective anticancer agents and treatment combinations.

Ensuring participant safety while maintaining the scientific integrity of clinical research requires integrating multidisciplinary expertise. Nurses have long played an active role in clinical research; however, the formal recognition of the Clinical Trial Nurse (CTN) as a specialized professional, together with the definition of the competencies required for this role, has emerged only relatively recently (4). Within clinical research teams, this professional is variously referred to as a Clinical Research Nurse (CRN), Study Nurse (SN), or Clinical Trial Nurse (CTN), across oncology and other clinical settings (5,6).

The CTN plays a pivotal role in supporting the growing number of oncology clinical trials while addressing the increasingly complex needs of patients with cancer (4). Core responsibilities include protocol review, patient recruitment and follow-up, data collection, education of clinical staff, administration of Investigational Medicinal Products (IMPs), management of treatment-related toxicities, and patient education (7). As an integral member of the multidisciplinary research team, the CTN serves as both an operational coordinator among healthcare professionals and a key point of contact for patients. The therapeutic relationship established with participants promotes treatment adherence, reduces dropout rates, and improves the overall trial experience by ensuring continuous assessment and management of patients' care needs. Furthermore, through ongoing education of ward nursing staff, the CTN supports continuity of care and contributes to patient safety throughout the entire study pathway (8).

Despite the increasing recognition of this role, the international literature continues to report substantial heterogeneity in the definition of CTN responsibilities, expected competencies, educational requirements, and professional scope. Consequently, job titles, role definitions, and job descriptions vary considerably across countries and healthcare systems (9). In Italy, Catania et al. (10) highlighted that the CTN's role in oncology remains insufficiently investigated and lacks formal recognition, in contrast to countries such as the United States, Canada, and the United Kingdom. This has generated ongoing debate regarding both the specialist nature of the role and the educational requirements necessary to perform it, with important implications for the quality and consistency of clinical trial processes.

These challenges are even more pronounced in pediatric hemato-oncology, where patient vulnerability, family-centered care, the frequent conduct of early-phase clinical trials, the management of acute and long-term toxicities, and prolonged follow-up require highly specialized and integrated competencies. In this setting, CTNs must combine advanced clinical expertise - such as the management of complex infusions and innovative therapies - with the ability to coordinate highly procedural clinical protocols, methodological competencies in Good Clinical Practice (GCP), data management and quality assurance, effective communication with children and caregivers, and a thorough understanding of ethical and legal issues, including informed consent and pediatric assent procedures, privacy protection, and continuity of care across hospital, school, and community settings. The absence of shared competency standards hampers the consistent development of these capabilities and contributes to variability in both patient care and protocol implementation. The complexity of the CTN role in pediatric hemato-oncology is summarized in Table 1, which presents the seven competency domains identified by Mampieri et al.

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(9) through a systematic review of the literature: clinical competencies, methodological competencies, communication and interpersonal competencies, autonomy, critical thinking, leadership, and teamwork.

Table 1. *Competency domains of the Clinical Trial Nurse identified in the studies included in the systematic review.*

Author, Year	Clinical Competencies	Methodological Competencies	Communication and interpersonal competencies	Autonomy	Critical Thinking	Leadership	Teamwork
Ocker and Plank, 2000		X	X		X		
Fishwick et al., 2002			X			X	X
Ehrenberger and Lillington, 2004	X	X	X			X	X
Catania et al., 2008	X	X	X			X	X
Liptrott et al., 2009	X	X		X	X		X
Nagel et al., 2010	X	X	X	X	X	X	X
Lubejko et al., 2011	X	X	X		X	X	
Catania et al., 2012	X	X	X			X	X
ONS, 2016	X	X	X	X	X	X	
Milani et al., 2017	X	X	X				
Ness and Royce, 2017	X	X	X	X	X	X	
Purdom et al., 2017	X	X	X	X	X	X	X
Showalter et al., 2017		X			X	X	
Choi and Park, 2018	X	X	X		X	X	
Black and Kulkarni, 2020	X	X	X	X	X	X	X

RATIONALE

Building upon these premises, the present methodological framework development study aimed to develop a national Core Curriculum and Job Description for Clinical Trial Nurses (CTNs) working in pediatric hemato-oncology. The framework was developed by integrating evidence from an international systematic review (9) and empirical findings from a multicenter observational study conducted across centers of the Italian Association of Pediatric Hematology and Oncology (AIEOP) (11).

Within the Italian healthcare system, the CTN role should also be interpreted in light of the Italian Medicines Agency

(AIFA) Determination No. 809/2015, which establishes the minimum requirements for healthcare facilities conducting Phase I clinical trials (12). This regulatory framework highlights the need for documented and continuously updated competencies in clinical research, particularly regarding mandatory Good Clinical Practice (GCP) training, protocol-specific procedures, patient safety, and the management of clinical emergencies, including Basic Life Support and Defibrillation (BLS-D) certification for personnel working in Phase I Units (12).

Accordingly, this study sought to address the need for a standardized competency framework by clearly defining the CTN profile in pediatric hemato-oncology and translating it into a national Core Curriculum and Job Description. The proposed framework aims to support education, clinical practice, and research quality by explicitly defining competencies, responsibilities, and professional functions, while promoting quality, patient

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safety, and consistency with international standards within the Italian pediatric setting. Within this perspective, the CTN is recognized as a key professional responsible for translating clinical trial protocols into safe clinical practice and ensuring continuity of care throughout the entire research pathway (4–6).

OBJECTIVE

The objective of this methodological framework development study was to develop a national Core Curriculum and Job Description for Clinical Trial Nurses in pediatric hemato-oncology. The proposed framework is intended to support standardized educational pathways, transparent competency assessment, and consistent professional role definition across the Italian healthcare system. Furthermore, it aims to promote a measurable, certifiable model of nursing competence that improves the quality of care delivered in pediatric hemato-oncology clinical trials, ultimately enhancing the experiences and outcomes of children and their families.

METHODOLOGY FOR THE DEVELOPMENT OF THE CORE CURRICULUM

The national Core Curriculum for Clinical Trial Nurses in pediatric hemato-oncology was developed through an integrated methodological process combining evidence from an international systematic review (9) with empirical findings obtained from the multicenter survey conducted across centers of the Italian Association of Pediatric Hematology and Oncology (AIEOP) (11).

The development process aimed to identify the specialist competencies defining the professional profile of the CTN and to establish a shared national framework to guide education and professional development. International competency frameworks for Clinical Trial Nurses served as the principal conceptual and methodological reference for developing a competency-based model grounded in the analysis of professional functions, required knowledge, and expected behaviors within pediatric hemato-oncology clinical trials.

The development process comprised three sequential phases:

1. Identification of core competencies through the systematic review of the literature (9), which identified the fundamental clinical, methodological, organizational, and communication competencies characterizing Clinical Trial Nursing practice.
2. Analysis of the Italian context based on findings from the AIEOP multicenter observational study (11), providing an overview of the current organization and characteristics of the CTN role across Italian pediatric hemato-oncology centers.
3. Development of the competency framework and Job Description, integrating evidence from the literature with empirical findings into a comprehensive national Core Curriculum. This framework provides the basis for future educational standards, competency certification pathways, and formal recognition of the CTN role within pediatric clinical research.

This structured methodology was designed to ensure that the proposed Core Curriculum is both evidence-based and consistent with the organizational and professional characteristics of the Italian healthcare system. Ultimately, it aims to support the development of a specialist nursing profile integrating advanced clinical expertise, methodological competencies, and research management skills, while promoting nationally consistent quality standards.

The proposed Core Curriculum is grounded in the assumption that competency represents the central and dynamic element of professional development. Accordingly, Competency-Based Education (CBE) was adopted as the educational framework underpinning the curriculum design, emphasizing the acquisition of integrated knowledge, skills, and professional behaviors that can be translated into safe, effective, and context-specific clinical practice.

RESULTS

National Core Curriculum for the Clinical Trial Nurse

The proposed Core Curriculum organizes the CTN role within an integrated competency framework that translates clinical trial protocols into safe, traceable, and ethically compliant clinical practice. Positioning specialist competencies at the core of the curriculum establishes a direct relationship between education, professional

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practice, and measurable outcomes—including patient and family safety, protocol integrity, and data quality—while providing a structured basis for competency assessment, continuous improvement, and professional identity development within the Italian pediatric healthcare system.

Competency Framework

Table 2 summarizes the competency domains defining the role of Clinical Trial Nurses in pediatric hemato-oncology

Table 2. *Competency framework for the Clinical Trial Nurse in pediatric hemato-oncology.*

COMPETENCY DOMAIN	MACRO-AREAS OF COMPETENCE
Clinical Competencies	1. Planning and delivering nursing care for children and adolescents enrolled in high-complexity clinical trials, ensuring implementation of the nursing process, protocol adherence, patient and family safety, and the appropriate execution of all trial-related procedures. 2. Providing advanced clinical surveillance and intensive participant monitoring through the early identification, assessment, management, and reporting of treatment-related toxicities and adverse events (CTCAE), while ensuring compliance with protocol-defined assessment windows and continuity of care.
Methodological Competencies	1. Ensuring clinical governance and methodological compliance throughout the clinical trial, from study start-up to close-out, in accordance with Good Clinical Practice (GCP), applicable regulations, and protocol requirements. 2. Managing study documentation, data quality, and process traceability, including data collection, electronic data management systems, protocol deviation management, and participation in monitoring visits, audits, and inspections.
Communication and Interpersonal Competencies	3. Coordinating the operational and logistical aspects of the study, including biological sample management, study materials, centralized services, and scheduling of protocol-required visits and procedures. 1. Providing therapeutic education and supporting children and their families throughout the clinical trial, promoting protocol understanding, treatment adherence, and informed participation. 2. Delivering specialist education and consultation to healthcare professionals involved in the trial, ensuring standardized practice, competency transfer, and documentation of training activities.
Autonomy	1. Independently managing high-complexity nursing processes related to investigational medicinal products (IMPs), including allocation, preparation, accountability, compliance verification, and implementation of protocol-specific procedures. 2. Assuming operational responsibility for critical study-related processes while ensuring continuity of care, patient safety, and regulatory compliance within the scope of professional practice.
Critical Thinking	1. Applying advanced clinical reasoning to risk management through the early identification of critical issues, grading of adverse events, and activation of protocol-defined escalation pathways. 2. Contributing to the continuous improvement of clinical trial quality by analyzing protocol deviations, identifying root causes, and participating in the development of corrective and preventive actions (CAPA).
Leadership	1. Coordinating nursing research processes by promoting quality, patient safety, standardization of clinical practice, and professional development within the nursing team.

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COMPETENCY DOMAIN	MACRO-AREAS OF COMPETENCE
	2. Providing organizational and methodological support for clinical trial conduct by coordinating briefings, debriefings, site initiation visit (SIV), preparation, monitoring activities, and implementation of study procedures.
Teamwork	1. Promoting interdisciplinary coordination and multiprofessional collaboration throughout the conduct of clinical trials, ensuring continuity of care and protocol compliance. 2. Managing organizational interfaces between clinical research, patient care, and support services by collaborating with investigators, Clinical Research Associates (CRAs), hospital pharmacies, laboratories, data managers, and other healthcare professionals to ensure data quality, protocol compliance, timely study conduct, and participant safety.

Figure 1 illustrates the competency model, which places the child and family at the center, together with the three overarching objectives of the role: patient safety, data quality, and protocol integrity

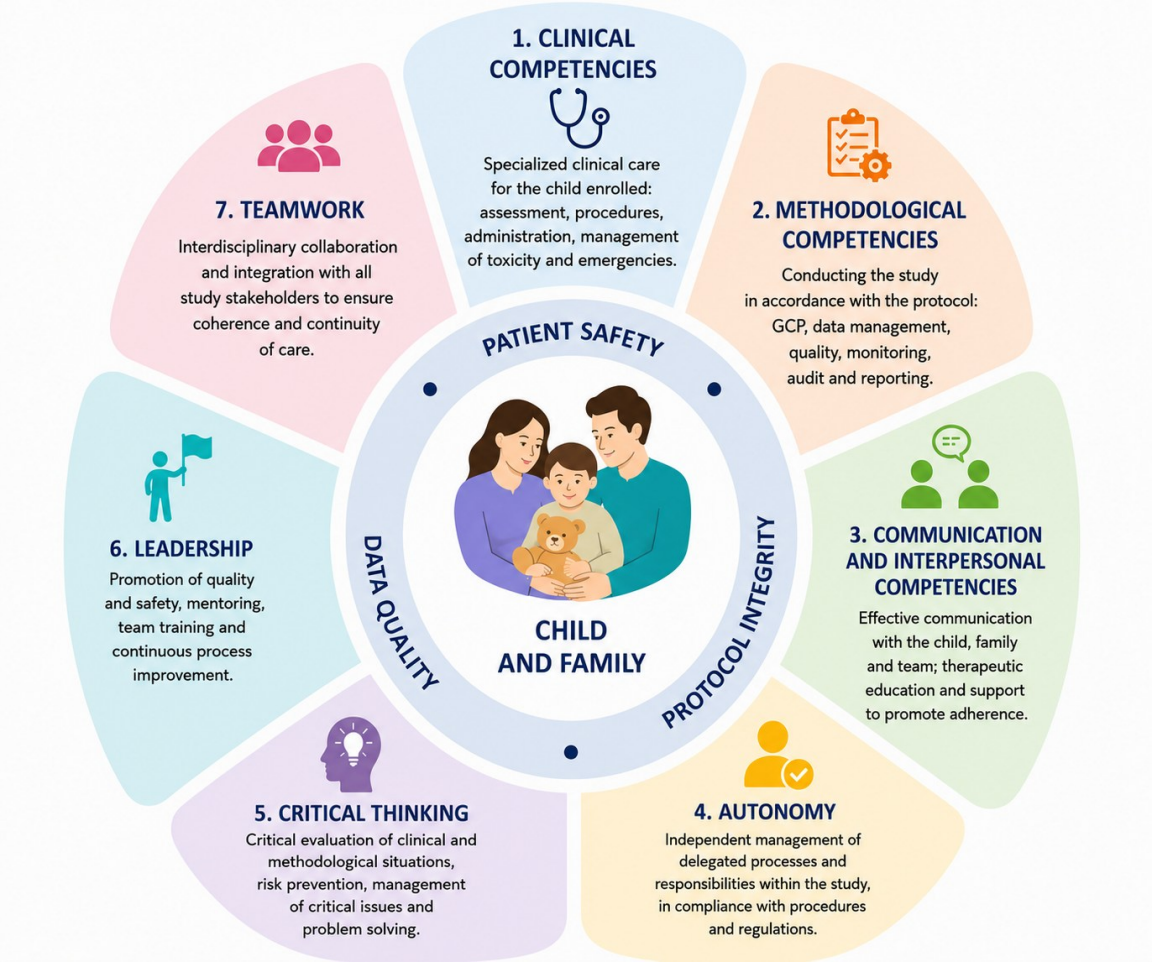

Figure 1. The competency framework for the Clinical Trial Nurse in Pediatric Hemato-Oncology

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Job Description

The formalization of a Job Description for the Clinical Trial Nurse (CTN) in pediatric hemato-oncology aims to reduce the role ambiguity arising from heterogeneous clinical practices and to align competencies and responsibilities with ethical and regulatory requirements and research quality standards, thereby ensuring patient safety, protocol integrity, and data quality.

The Job Description provides a coherent framework linking what the CTN role is expected to be (expected competencies, responsibilities, and professional standards) with how it is performed in practice (actual activities, outcomes, and process traceability), serving as a bridge between the competency framework and work organization. Its implementation across pediatric hemato-oncology centers represents a prerequisite for ensuring consistency, safety, and quality in the conduct of clinical trials while supporting recognition of the CTN's specialist contribution within the Italian pediatric oncology network. In addition, it fulfills both descriptive and regulatory functions by clarifying role expectations, defining the scope of practice, and providing reference criteria for professional organizations and performance evaluation.

Within this framework, the primary objectives of the CTN Job Description are:

1. Role clarity and accountability: to define the CTN's responsibilities, decision-making authority, and level of professional autonomy throughout the entire clinical trial lifecycle, clearly distinguishing them from those of other research professionals, including the Principal Investigator (PI), Study Coordinator, Clinical Research Associate (CRA), and Data Manager. The Job Description also specifies organizational interfaces through responsibility matrices in order to minimize role overlap and eliminate areas of unclear accountability.
2. Ethical and regulatory compliance and quality assurance: to align CTN activities and responsibilities with the principles of Good Clinical Practice (GCP), institutional standard operating procedures, and protocol requirements, with particular attention to pediatric informed consent and assent procedures, investigational medicinal product (IMP) accountability and traceability, and adverse event management according to the Common Terminology Criteria for Adverse Events (CTCAE) (13).
3. Translation of the competency framework into observable standards: to translate the seven competency domains (clinical, methodological, communication and interpersonal, autonomy, critical thinking, leadership, and teamwork) into observable professional behaviors, measurable outcomes, and assessment tools (e.g., checklists, OSCE/mini-CEX, audit trails, and professional portfolios). Representative performance indicators include the proportion of protocol visits completed within predefined time windows, the completeness and accuracy of study data collection forms, time to resolution of data queries, appropriate reconciliation of investigational medicinal products, and consistency in adverse event grading according to CTCAE criteria.
4. Organizational standardization and multiprofessional integration: to reduce variability across centers by defining minimum role requirements together with standardized documentation and operational processes (e.g., visit scheduling, biological sample and ECG logistics, and information flows), while structuring briefings, debriefings, and clinical handovers through agreed communication channels and timelines to facilitate effective collaboration among all professionals involved in the clinical trial.
5. Professional development and continuous improvement: to guide basic, specialist, and advanced educational pathways, mentoring activities, and periodic competency assessments, documenting progression from supervised practice to the independent management of complex clinical research processes. Furthermore, findings from monitoring activities and audits

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should be used to update procedures, educational interventions, and organizational practices.

See *Appendix 1. Job Description for the Clinical Trial Nurse in Pediatric Hemato-Oncology*.

Performance Indicators and Expected Outcomes

The operational implementation of the Core Curriculum and Job Description for Clinical Trial Nurses (CTNs) in pediatric hemato-oncology requires a measurement framework that translates competencies into observable, traceable, and comparable outcomes across the entire clinical trial lifecycle, including study initiation, conduct, monitoring, and close-out. In a setting characterized by substantial methodological and relational complexity, performance indicators serve a purpose beyond administrative monitoring. Consistent with Donabedian's conceptual framework (14), they establish measurable links between structures, processes, and outcomes, thereby documenting patient and family safety, methodological integrity, and the scientific robustness of study data.

From a clinical perspective, key performance indicators include the timely completion of protocol-required visits and procedures, compliance with and traceability of investigational product administration (dose, route, administration time, and, where applicable, batch number), preservation of biological sample integrity during the pre-analytical phase, and timely submission of diagnostic records for central review. These indicators provide objective evidence of protocol adherence to the mandatory elements defined by the SPIRIT 2013 Statement (15), while ensuring compliance with Good Clinical Practice (GCP). Expected outcomes include fewer protocol window deviations, reduced rework associated with procedural errors, and improved continuity of care across inpatient, day-hospital, and outpatient settings, ultimately contributing to patient safety and overall quality of care.

Within the domains of patient safety and pharmacovigilance, performance indicators should capture the timely recognition of clinical signs and symptoms, accurate documentation, and consistent grading of adverse events according to internationally recognized classifications, particularly the Common Terminology Criteria for Adverse Events (CTCAE v5.0) (13). Additional indicators include timely reporting of serious adverse events within regulatory timelines and accurate reconciliation of investigational medicinal products, both of which represent proxies for compliance with international standards and the requirements of Regulation (EU) No. 536/2014 (16). Expected outcomes include improved comparability of safety data, fewer protocol deviations and medication-related near misses, and enhanced management of clinical risk in pediatric research.

Data quality and verifiability may be assessed through indicators such as the completeness and accuracy of electronic Case Report Forms (eCRFs), time required to resolve data queries, concordance between source documents and eCRFs during Clinical Research Associate (CRA) monitoring visits, timely updating of essential study documents (including protocol amendments, delegation logs, and training records), and overall readiness for monitoring visits, audits, and regulatory inspections. Expected outcomes include reliable and verifiable research data, shorter resolution times for non-conformities, successful audit outcomes, and increased scientific credibility of the clinical trial, consistent with GCP principles and CONSORT recommendations.

Within the communication, interpersonal, and advocacy domain, indicators assess the quality of therapeutic education provided to children and their families, including documentation of educational encounters and the use of teach-back strategies, adherence to home-based treatment, implementation and completeness of patient- and family-reported outcomes, and the appropriateness of the informed consent and pediatric assent process. Expected outcomes include greater family empowerment, more appropriate healthcare utilization, improved treatment adherence, and enhanced integration of patient-reported outcomes into clinical decision-making.

The domains of professional autonomy and critical thinking may be evaluated through indicators that assess the accuracy of adverse event grading, the quality and timeliness of clinical reports, participation in the analysis of protocol deviations and nonconformities, and the effectiveness of corrective and preventive actions (CAPA). Expected outcomes include greater process resilience, fewer recurrent critical events, improved risk prevention, and enhanced organizational stability, ultimately

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strengthening both ethical oversight and methodological rigor.

Finally, leadership and teamwork may be evaluated through indicators reflecting the implementation of structured briefings and debriefings, the quality of handovers across care settings, documentation of internal training and mentoring activities, and active participation in site initiation visits and monitoring visits. Expected outcomes include stronger multiprofessional collaboration, fewer areas of unclear responsibility, and the establishment of a continuous organizational learning culture supported by Plan–Do–Check–Act (PDCA) cycles, ultimately improving both center performance and the perceived quality of care (17).

Overall, a set of performance indicators aligned with the proposed competency framework and corresponding professional responsibilities enables objective evaluation of the CTN's specialist contribution to pediatric patient safety, protocol integrity, and scientific data quality, while simultaneously promoting regulatory compliance and continuous professional development. Alignment with internationally recognized frameworks and standards—including SPIRIT, ICH-GCP, CONSORT, FDA Patient-Reported Outcome (FDA-PRO) Guidance, and ICH E11—also facilitates comparisons within and across centers and enhances preparedness for monitoring visits and regulatory inspections, thereby translating the Core Curriculum and Job Description into measurable, documentable outcomes.

DISCUSSION

A Competency-Based Approach

In pediatric hemato-oncology, Competency-Based Medical Education (CBME) provides an appropriate framework for defining the competencies required of Clinical Trial Nurses (CTNs) through observable, measurable learning outcomes. Consistent with this approach, the present study developed a Core Curriculum, a Job Description, and a framework of performance indicators and expected outcomes to establish a structured model for defining the CTN role and guiding education, competency assessment, and professional development within pediatric hemato-oncology clinical research.

Given the high complexity of pediatric clinical research pathways—including combination therapies, high-risk chemotherapy, immunotherapy, and advanced therapeutic medicinal products—the CTN requires specialist competencies that integrate clinical, methodological, organizational, and ethical and regulatory dimensions. These competencies are essential to ensure both the quality of clinical trials and the protection of children and their families, encompassing the safe administration of investigational treatments, management of adverse events and supportive care, coordination with hospital laboratories and pharmacy services, and the appropriate management of informed consent and pediatric assent procedures. The literature consistently indicates that developing these competencies requires structured, multilevel educational pathways that support both newly qualified nurses and experienced professionals transitioning from other clinical settings (17). Furthermore, pediatric oncology nursing is characterized by a family-centered model of care that extends across the entire care continuum and has been associated with improved patient and family satisfaction, greater treatment adherence, and better clinical outcomes (18–20).

Evidence from nursing research further demonstrates that professional competence is closely associated with quality of care, patient safety, and healthcare outcomes, underscoring the need for robust, standardized competency frameworks (21–23).

Within the Italian healthcare system, recognition of specialist and advanced nursing competencies remains an evolving issue. Although the current regulatory framework provides opportunities for professional development (24), its implementation remains heterogeneous across healthcare and research settings. Two major implications therefore emerge: first, the need for specialist education and continuous professional development capable of supporting competencies appropriate to increasingly complex clinical and research pathways; and second, the value of a shared operational framework for describing, assessing, and monitoring professional progression (25).

Accordingly, the present methodological framework proposes a competency progression model that is consistent with the Italian professional framework while

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linking competencies to observable behaviors and measurable performance indicators. The model identifies four progressive levels of professional development—foundation, specialist, expert clinician or coordinator, and advanced specialist—conceived as a continuum characterized by increasing autonomy, responsibility, and professional complexity.

Within the Italian context, nursing competency progression continues to evolve alongside an expanding debate concerning the recognition of advanced nursing practice, specialist competencies, and professional career pathways. Rather than replacing the existing legislative or contractual framework, the proposed model is intended as a practical tool to promote greater consistency in defining the CTN role while supporting recognition of the specialist competencies required for pediatric hemato-oncology clinical research. Consequently, the framework may serve as a reference for designing educational programs and for establishing shared criteria for professional responsibility, competency assessment, and workforce development within healthcare organizations.

Educational and Professional Requirements for Clinical Trial Nurses

In the context of clinical research, compliance with Good Clinical Practice (GCP) is a fundamental requirement rather than a mere formal obligation. Clinical trials conducted without adherence to GCP cannot generate evidence suitable for supporting the marketing authorization of investigational medicinal products, whether involving novel compounds, new therapeutic combinations, or alternative treatment strategies. Beyond ensuring the reliability and verifiability of research findings, compliance with international standards primarily safeguards the rights, safety, and well-being of research participants, in accordance with the ethical principles established by the Declaration of Helsinki.

Accordingly, a healthcare institution's ability to conduct clinical trials depends on the availability of appropriately trained personnel, including both medical and non-medical professionals, with competencies in clinical research sufficient to ensure full compliance with GCP requirements (26). This must be complemented by an appropriate organizational and technological infrastructure, including regularly maintained and certified equipment, dedicated facilities with controlled access for research activities, and secure systems for the storage and archiving of essential study documents. Only the integration of qualified personnel with an appropriate research infrastructure can ensure methodological quality, process transparency, and effective protection of research participants.

Access to the CTN role in pediatric hemato-oncology should require postgraduate academic education, such as a First- or Second-Level Master's Degree in Clinical Research, a Master's Degree, or a Doctor of Philosophy (PhD). Eligibility for professional recognition and contractual appointment as a CTN should include one of the following educational and professional pathways:

- A Bachelor's Degree in Nursing, together with a postgraduate Master's Degree in Clinical Research;
- A Bachelor's Degree in Nursing, together with a Master's Degree and/or a Doctor of Philosophy (PhD);
- A Bachelor's Degree in Nursing combined with at least 2 years of clinical experience and 3 years of supervised clinical research experience under the guidance of a senior Clinical Trial Nurse.

These educational pathways ensure the acquisition of the knowledge, skills, and competencies required for protocol implementation, effective communication with investigators and research participants, and the critical appraisal of scientific evidence.

Implications for Clinical Practice From a practical perspective, the proposed framework provides pediatric hemato-oncology centers with an immediately applicable tool for standardizing clinical research processes, strengthening preparedness for monitoring visits, audits, and regulatory inspections, and promoting continuous organizational learning. From a professional policy perspective, it provides an evidence-informed basis for establishing national minimum standards, designing

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multilevel educational pathways, and formally recognizing the specialist competencies of Clinical Trial Nurses.

Nevertheless, the successful implementation of the proposed framework will require addressing several organizational challenges. Structural variability among pediatric hemato-oncology centers, the unequal availability of dedicated research personnel, differences in CTN employment models, and the absence of nationally shared competency standards may all limit widespread implementation. At the same time, the increasing ethical and regulatory complexity of pediatric clinical trials further emphasizes the need to formally recognize professionals with specialist expertise in participant protection, Good Clinical Practice (GCP) implementation, and the coordination of clinical research activities.

The principal contribution of this methodological framework development study lies in translating the broad concept of professional competence into an operational framework that supports curriculum design, workforce organization, and competency assessment.

This study systematically defined the role of the Clinical Trial Nurse (CTN) in pediatric hemato-oncology, demonstrating that the methodological quality of clinical trials, the protection of pediatric participants, and continuity of care depend, in part, on the availability of a clearly defined and measurable specialist nursing role. The available evidence, together with the current ethical and regulatory framework and existing organizational practices, highlights three major challenges: the absence of nationally shared standards for CTN education and role definition; substantial variability in professional responsibilities and operational processes across Italian centers; and the need for common tools capable of making the nursing contribution to scientific rigor and patient- and family-centered care both visible and measurable. To address these challenges, the present study proposes an integrated framework combining a competency model, a formal Job Description, and a comprehensive system of performance indicators and expected outcomes.

Several limitations should nevertheless be acknowledged. The proposed performance indicators require empirical validation, greater integration of patient and family perspectives is needed when defining relevant outcomes, and further research should investigate the impact of the CTN role on both clinical outcomes and trial quality. Future studies should therefore focus on validating competency assessment tools, evaluating the clinical and organizational outcomes associated with implementation of the proposed Job Description, and examining the economic implications of introducing this specialist nursing role.

In conclusion, defining the competencies and responsibilities of Clinical Trial Nurses in pediatric hemato-oncology extends beyond a purely formal exercise and represents a fundamental prerequisite for ensuring research quality, patient safety, and scientific integrity. The coordinated implementation of the competency framework, Job Description, and performance indicators proposed in this study represents a practical step toward establishing a shared national reference model that integrates clinical excellence, methodological rigor, and child- and family-centered care.

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APPENDICES Appendix 1.

Job Description of the Clinical Trial Nurse in Pediatric Hemato-Oncology (in both English and Italian original language)

English Version

Position:	Senior Clinical Trial Nurse	**Category**	Healthcare Professional
Department:	Pediatric Hemato-Oncology	**Continuing Education Credits (ECM):**	
Reports to:	Nurse Manager (Pediatric Hemato-Oncology Unit)	**Organizational Supervisor:**	Director of Nursing and Allied Health Professions
Employment Grade:		**Employment Type:**	Full-time

Job Description

Role and Responsibilities

The Senior Clinical Trial Nurse (CTN) in pediatric hemato-oncology is the healthcare professional responsible for providing specialist nursing care to pediatric patients enrolled in clinical trials and for ensuring the operational implementation of research protocols across different care settings, including inpatient wards, day hospitals, and outpatient clinics. The CTN serves as the clinical and methodological interface within the multidisciplinary research team, ensuring integration between the care needs of children and their families and the ethical, regulatory, and methodological requirements of clinical research.

The position requires a minimum of three years of professional experience, together with specialist training in pediatric hemato-oncology and demonstrated expertise in managing highly complex clinical situations and actively contributing to their resolution. Expected performance is consistent with the advanced level of clinical complexity inherent to pediatric hemato-oncology and the conduct of clinical trials across different healthcare settings and transitions of care.

The role requires proficiency in the nursing process, methodological competencies in clinical trial management, advanced communication and advocacy skills, critical thinking, professional autonomy, teamwork, and leadership focused on quality improvement and patient safety. Consequently, the position entails a high level of professional responsibility, including:

- Individual professional accountability for all activities related to the role;
- Shared responsibility within the multidisciplinary team for delegated and collaborative activities;
- Ethical responsibility for internal and external professional actions and communications;
- Direct responsibility for the education and supervision of newly appointed nurses and healthcare support workers;
- Responsibility for continuous professional development, including educational and facilitation activities.

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Preferably, candidates should hold a First-Level Master's Degree relevant to the field (Pediatrics, Oncology, or Clinical Research), a Master's Degree (MSc), and/or a Doctor of Philosophy (PhD).

For clinical activities, the CTN reports to the Nurse Manager and the Principal Investigator (PI) and performs periodic self-assessment of the required professional competencies and performance standards.

Core Competencies of the Clinical Trial Nurse in Pediatric Hemato-Oncology

Competency Domain	Core Competencies
Clinical Competencies	**1. Planning and delivering nursing care for children and adolescents enrolled in high-complexity clinical trials**, ensuring implementation of the nursing process, protocol adherence, patient and family safety, and the appropriate execution of all trial-related procedures.
	2. Providing advanced clinical surveillance and intensive participant monitoring through the early identification, assessment, management, and reporting of treatment-related toxicities and adverse events (CTCAE), while ensuring compliance with protocol-defined assessment windows and continuity of care.
Methodological Competencies	**1. Ensuring clinical governance and methodological compliance throughout the clinical trial**, from study start-up to close-out, in accordance with Good Clinical Practice (GCP), applicable regulations, and protocol requirements.
	2. **Managing study documentation, data quality, and process traceability, including data collection, electronic data management systems**, protocol deviation management, and participation in monitoring visits, audits, and inspections.
	3. Coordinating the operational and logistical aspects of the study, including management of biological samples, study materials, centralized services, and scheduling of protocol-required visits and procedures.
Communication and Interpersonal Competencies	1. **Providing therapeutic education and supporting children and their families throughout the clinical trial**, promoting protocol understanding, treatment adherence, and informed participation.
	2. Delivering specialist education and consultation to healthcare professionals involved in the trial, ensuring standardized practice, competency transfer, and documentation of training activities.
Professional Autonomy	**1. Independently managing high-complexity nursing processes related to investigational medicinal products (IMPs)**, including allocation, preparation, accountability, compliance verification, and implementation of protocol-specific procedures.
	2. Assuming operational responsibility for critical study-related processes while ensuring continuity of care, patient safety, and regulatory compliance within the scope of professional practice.
Critical Thinking	**1. Applying advanced clinical reasoning to risk management** through the early identification of critical issues, grading adverse events, and activation of protocol-defined escalation pathways.
	2. Contributing to the continuous improvement of clinical trial quality through analysis of protocol deviations, identification of root causes, and participation in the development of corrective and preventive actions (CAPA).
Leadership	**1. Coordinating nursing research processes** by promoting quality, patient safety,

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	standardization of clinical practice, and professional development within the nursing team.
	2. Providing organizational and methodological support for clinical trial conduct by coordinating briefings, debriefings, Site Initiation Visit (SIV) preparation, monitoring activities, and implementation of study procedures.
Teamwork	**1. Promoting interdisciplinary coordination and multiprofessional collaboration** throughout the conduct of clinical trials, ensuring continuity of care and protocol compliance.
	2. Managing organizational interfaces between clinical research, patient care, and support services by collaborating with investigators, Clinical Research Associates (CRAs), hospital pharmacy services, laboratories, data managers, and other healthcare professionals to ensure data quality, protocol compliance, timely study conduct, and participant safety.

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Approved by:	Directorate of Nursing and Allied Health Professions	Date:	
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Document Review:	Two years after publication	Date:	

Italian Original Version:

Ruolo:	Infermiere di ricerca clinica *senior*	**Tipologia:**	Sanitario
Reparto:	Emato-oncologia pediatrica	**Crediti ECM**	
Responsabile	Infermiere coordinatore (U.O. Emato-oncologiapediatrica)	**Responsabile Org.**	Dirigente delle Professioni Sanitarie
Livello contrattuale		**Tipologia contratto**	Tempo pieno
Job Description			

Ruolo e Responsabilità

L'infermiere di ricerca clinica *senior* in emato-oncologia pediatrica (specialista) è il professionista sanitario che ha la responsabilità dell'assistenza specialistica infermieristica ai pazienti pediatrici emato-oncologici arruolati in studi clinici, nonché dell'implementazione operativa del protocollo di ricerca nei diversi *setting* (degenza, *day hospital*, ambulatori). Opera come snodo clinico-metodologico dell'*équipe*, garantendo l'integrazione tra requisiti

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assistenziali del bambino/famiglia e vincoli etico-regolatori/metodologici dello studio. Possiede almeno 3 anni di esperienza e una formazione specifica nell'area pediatrica emato-oncologica, con comprovata capacità di governo dei problemi clinico-assistenziali ad alta complessità e di partecipazione attiva alla loro risoluzione. Le *performance* attese sono quelle specialistiche e coerenti con l'alta complessità clinico-assistenziale propria dell'emato-oncologia pediatrica e della conduzione di studi clinici nei diversi *setting* e nelle transizioni di cura.

Il profilo richiede padronanza del processo infermieristico, competenze metodologiche di gestione dello studio, capacità comunicativo-relazionali e di *advocacy*, pensiero critico, autonomia decisionale, lavoro in *team* e *leadership* orientata alla qualità e alla sicurezza. Ne consegue un livello di responsabilità elevato che comprende: una responsabilità professionale individuale su tutte le attività inerenti al ruolo, una responsabilità di *équipe* nelle attività interprofessionali (delega e attribuzioni di attività), una responsabilità etica sulle azioni e le comunicazioni interne ed esterne, una responsabilità diretta sulla formazione/tutoraggio dei nuovi infermieri ed operatori sociosanitari, una responsabilità sull'aggiornamento professionale anche in qualità di formatore e di facilitatore. È preferibile il possesso di un Master di I livello coerente con l'area (pediatria/oncologia/ricerca clinica), e/o Laurea Magistrale (LM) e/o Dottorato (*PhD*).

Risponde, per le attività assistenziali, all'infermiere coordinatore e al medico responsabile/*Principal Investigator* ed effettua autovalutazioni periodiche delle *performance* richieste.

Macro-competenze dell'infermiere di ricerca in emato-oncologia pediatrica:

Competenze cliniche	**1. Pianificazione e gestione assistenziale del bambino e dell'adolescente arruolato in studi clinici sperimentali ad alta complessità**, garantendo l'applicazione del processo infermieristico, l'aderenza al protocollo, la sicurezza del paziente e della famiglia e la corretta esecuzione delle procedure previste dal *trial*.
	2. Sorveglianza clinica avanzata e monitoraggio intensivo del partecipante, mediante identificazione precoce, valutazione, gestione e segnalazione delle tossicità e degli eventi avversi (CTCAE), assicurando il rispetto delle finestre temporali del protocollo e la continuità assistenziale.
Competenze metodologiche	**1. Garanzia della *Clinical Governance* e della *compliance* metodologica del trial**, assicurando la conduzione dello studio dalla fase di *start-up* alla chiusura secondo Good Clinical Practice (GCP), normativa vigente e requisiti del protocollo.
	2. Gestione integrata della documentazione di studio, della qualità dei dati e della tracciabilità dei processi, comprendente raccolta dati, gestione dei sistemi elettronici, monitoraggio delle deviazioni, partecipazione a monitoraggi, audit e ispezioni.
	3. Coordinamento operativo dei flussi tecnico-logistici dello studio, inclusa la gestione dei campioni biologici, dei materiali di studio, dei servizi centralizzati e della programmazione delle visite e delle procedure previste dal protocollo.
Competenze comunicativo-relazionali	**1. Educazione terapeutica e accompagnamento del bambino e della famiglia nel percorso sperimentale**, favorendo la comprensione del protocollo, l'aderenza terapeutica e la partecipazione consapevole allo studio.
	2. Formazione e consulenza specialistica agli operatori coinvolti nel *trial*, garantendo uniformità operativa, trasferimento delle competenze e tracciabilità della formazione.
Autonomia	**1. Gestione autonoma dei processi assistenziali ad elevata complessità correlati ai medicinali sperimentali (IMP)**, comprendente assegnazione, preparazione, *accountability*, verifica della *compliance* e applicazione delle procedure

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	previste dal protocollo.
	2. Assunzione di responsabilità operative nella gestione dei micro-processi critici dello studio, assicurando continuità, sicurezza e conformità normativa nell'ambito delle competenze professionali.
Pensiero critico	**1. Applicazione del ragionamento clinico avanzato nella gestione del rischio clinico**, attraverso l'identificazione precoce delle criticità, la classificazione degli eventi avversi e l'attivazione dei percorsi di *escalation* previsti dal protocollo.
	2. Contributo al miglioramento continuo della qualità della sperimentazione clinica, mediante analisi delle deviazioni, individuazione delle cause e collaborazione alla definizione di azioni correttive e preventive (CAPA).
Leadership	**1. Coordinamento professionale dei processi infermieristici di ricerca clinica**, promuovendo qualità, sicurezza, standardizzazione delle pratiche e sviluppo delle competenze del team assistenziale.
	2. Supporto organizzativo e metodologico alla conduzione dello studio clinico, coordinando *briefing*, *debriefing*, attività preparatorie alle SIV, monitoraggi e implementazione delle procedure operative.
Team-work	**1. Coordinamento interdisciplinare e integrazione multiprofessionale nella conduzione dei *trial* clinici**, assicurando la continuità dei percorsi assistenziali e la corretta applicazione del protocollo.
	2. Gestione delle interfacce organizzative tra ricerca clinica, assistenza e servizi di supporto, collaborando con sperimentatori, CRA, farmacia, laboratori, *data management* e altri professionisti per garantire qualità dei dati, rispetto delle tempistiche e sicurezza del partecipante.

Redazione:	Gruppo lavoro infermieristico AIEOP	Data:	
Approvazione:	Direzione professioni sanitarie	Data:	
Emanazione	Direzione generale	Data	
Revisione documento	2 anni dall'emanazione	Data	

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