



Education pathways and key tasks for research nurses in Europe, results from a VACCELERATE online survey

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ABSTRACT

Aim: This article aims to provide a comprehensive overview of the educational pathways and responsibilities of research nurses in Europe, particularly focusing on their essential role in conducting research in clinical settings, including clinical trials, while adhering to ethical and regulatory standards.

Background: Research nurses play a crucial role in clinical research settings, especially in clinical trials, ensuring adherence to ethical and regulatory standards. Understanding their educational pathways and responsibilities is essential for promoting consistency and quality in research practices across Europe.

Design: Between October and November 2022, relevant European nursing education authorities, including those focused on research nursing, were contacted to participate in an online cross-sectional survey. The survey aimed to gather information about research nurse education and training in their respective countries.

Methods: The study followed a cross-sectional design. Contacts were made with European nursing education authorities based on recommendations from the VACCELERATE National Coordinators and the VACCELERATE Site Network. Participating organizations were invited to complete an online survey regarding research nurse education in their countries.

Results: Responses were obtained from 37 European countries, a response rate of 74%. The most common terms used to refer to nurses involved in clinical trials and epidemiological studies were "study nurse" (62%) and "clinical research nurse" and "research nurse" (43% each). The requirements to become a research nurse varied

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across countries, with a nursing degree necessary in 87% of countries and Good Clinical Practice (GCP) courses mandatory in 81%. Local providers of research nurse courses existed in 84% of countries, coordinated by online organisations (51%) or universities/hospitals (46%). The most common tasks assigned to research nurses were the administration of investigational medicinal products (from 78% in observational studies to 89% in phase IV trials) and blood sample processing (84% in phase II and IV trials).

Conclusions: This study provides valuable insights into research nurse education and tasks in European countries. It highlights the need for standardisation to enhance consistency and quality of training across Europe.

1. Introduction

Research nurses, also known as clinical research nurses or study nurses, are registered nurses who possess specialised skills in conducting research in clinical or healthcare settings (Grady and Edgerly, 2009). Research nurses receive their initial education to navigate the research world through a combination of formal education, training programs and practical experience (Viberg Johansson et al., 2022; King et al., 2022; Chen et al., 2022).

Many institutions offer certificate programs or advanced degrees, such as master's or doctoral degrees in nursing with a concentration in research. This provides a comprehensive theoretical foundation in research methodologies, biostatistics, data management and ethical considerations in research. Moreover, research education and training are a mainstay strategy targeted at the individual level. These programs are often multifaceted, encompassing experiential learning and often include a mentoring component¹. They are designed to equip nurses with the necessary skills to conduct research in healthcare settings. Furthermore, the on-the-job training under experienced research professionals plays a crucial role in honing their skills and acclimatizing them to the intricacies of conducting research in clinical or healthcare settings. Through this multifaceted approach to education and training, research nurses are prepared to effectively contribute to the design, implementation and management of various research activities (Viberg Johansson et al., 2022; King et al., 2022; Chen et al., 2022).

The research nurse expertise and contributions are vital in the design, implementation and management of various research activities, particularly clinical trials. These nurses have acquired strong clinical skills honed through their nursing background, ensuring they can effectively navigate through the complexities of research protocols and procedures. Research nurses' understanding of research methodologies and regulatory guidelines is crucial for the success and completion of studies. They collaborate closely with the research team, including principal investigators, physicians and other healthcare professionals, to ensure adherence to ethical standards and regulatory requirements. Research nurses facilitate the necessary approvals from institutional review boards (IRBs) or ethics committees, safeguarding the rights and welfare of study participants (Moro-Tejedor and Garcia-Pozo, 2023). Research nurses play an essential role in facilitating collaboration between the research and clinical settings. Through their specialized training and expertise in both fields, they are uniquely positioned to support non-research health care professionals, such as clinical nurses and unit staff, in the care of research participants outside of the research setting. This may involve coordination of care, education about research protocols and communication of important information about the study. In this way, research nurses can ensure that research participants receive consistent, high-quality care, regardless of whether they are in a research or clinical setting (Ballantine and Potter, 2023; Amicucci et al., 2022).

In Europe, the presence of collaborative research networks and at the same time diverse healthcare systems highlights the importance of Describing the educational paths and primary responsibilities of research nurses (VACCELERATE, 2023; Salmanton-García et al., 2022, 2023, 2021). By understanding these aspects, stakeholders can optimise the role of research nurses and strengthen research capacity across the region. Identifying areas that require additional emphasis in educational

programs enables the development of tailored training initiatives, ensuring research nurses possess the necessary skills and knowledge for their roles (Moro-Tejedor and Garcia-Pozo, 2023).

1.1. Aims/objectives

Here, we aim to provide a comprehensive overview of the current training landscape to become a research nurse in Europe. This includes understanding the educational requirements, the roles and responsibilities of research nurses and the specific skills and knowledge they need to effectively contribute to research activities. This understanding is crucial for optimizing the role of research nurses and strengthening research capacity across Europe.

2. Methods

Between October and November 2022, a cross-sectional quantitative descriptive study employing use of a survey, accessible online via the electronic case report form hosted at www.clinicalsurveys.net/uc/How2BecomeStudyNurse/. This questionnaire was meticulously crafted as part of the EFS Summer 2021 initiative, under the stewardship of the TIVIAN group based in Cologne, Germany.

The endeavour was characterized by a purposeful drive to ensure comprehensive representation of organisations in charge of nursing education, prompting targeted outreach to relevant European organizations, societies and institutions. This outreach took the form of personalized email invitations, extended with the aim of inviting their considered contributions. The collaborative undertakings of the VACCELERATE National Coordinators and the entities in the VACCELERATE Site Network (Salmanton-García et al., 2023) (accessible at www.vacceleerate.eu and www.vacceleerate.eu/site-network) played a pivotal role in identifying suitable entities in their respective national domains. The target countries encompassed those in Europe, as well as Israel, selected based on their extensive involvement in the development of research and educational projects. In case a response was obtained from regions outside those mentioned above, they would be excluded from subsequent analysis.

In anticipation of the subsequent analytical phases, a meticulous process of data validation was enacted. This process aimed to confirm the coherence and integrity of responses provided by each participating entity. The inquiries spanned a comprehensive spectrum, each addressing distinct dimensions of the intricate role inhabited by research nurses. These dimensions encompassed facets such as a) the varied nomenclature and terminological usages for the research nurse position, b) the exhaustive compilation of educational and training prerequisites required for aspiring research nurses, details regarding local institutions offering tailored courses for prospective research nurses, c) the temporal duration of training necessary to attain proficiency, d) the significance and availability of research nurse certification, e) the procedural requisites for the renewal of training and certification and f) a comprehensive explication of the multifaceted responsibilities entrusted to research nurses. In parallel, the responses were verified for inclusion/exclusion criteria through a rigorous validation process. Each respondent representing their respective organization was required to provide official credentials or authorization confirming their affiliation. This ensured that responses were provided by authorized representatives

with relevant expertise or insight into the subject matter. If you require further details on the specific mechanisms employed for validation, please let us know and we'd be happy to provide additional clarification.

The resultant dataset was thoughtfully presented through the use of pertinent statistical measures, including descriptive features, such as frequencies, percentages and appropriate ranges, affording a structured and comprehensive overview of the amassed information. SPSS v27.0 (SPSS, IBM Corp., Chicago, IL, United States) was used for all statistical analyses.

3. Results

Responses were obtained from organisations in 37 out of 50 European countries, representing a response rate of 74.0% (Fig. 1). Each organisation provided the answer for the respective country. Among the participating organisations, the most common term used to refer to nurses actively involved in clinical trials and observational studies was "study nurse", which was reported by 23 out of 37 countries (62.2%). Other commonly used terms included "clinical research nurse" and "research nurse", each of which was reported by 16 out of 37 countries (43.2%) (Table 1, Supplementary table 1).

The requirements to become a research nurse varied across countries. In 32 out of 37 countries (86.5%), a nursing degree was necessary. The exceptions to this requirement were Azerbaijan, Belarus, Croatia, Poland and the United Kingdom. The duration of a nurse's education also differed among countries, ranging from 2 years in Belarus to 5 years in Albania or Armenia (Fig. 2). The median duration across Europe was 4 years (interquartile range [IQR] 3–4). In 30 out of 37 countries (81.1%), Good Clinical Practice (GCP) courses were mandatory for becoming a research nurse, with the need to renew these accreditations regularly in

28 out of 30 countries (93.3%). Additionally, 25 out of 37 countries (67.6%) reported the need for additional specific training, which varied between territories but was not further specified (Table 1, Supplementary table 1).

In 31 out of 37 countries (83.8%), there was at least one local provider of research nurse courses. The coordination of such courses was commonly carried out by online organisations (19/37, 51.4%) and universities/hospitals (17/37, 45.9% each). Furthermore, in more than half of the countries (20/37, 54.1%), it was possible to participate in a research nurse course through other entities, either directly during a regular nurse's education (8/37, 21.6%) or in workers' unions (2/37, 5.4%). Only six countries (16.2%) reported a lack of research nurse courses: Azerbaijan, Croatia, Estonia, Israel, Poland and Slovenia. Certificates to validate the completion of the course were available in 25 out of 31 countries (80.6%) where research nurse courses were organised. The duration of such courses varied from less than one week in Norway to up to 27 months in Malta, where a master's degree was required. The median maximum duration was 3 months (IQR 1–12). Renewal of the research nurse course was reported to be necessary in 15 out of 31 countries (48.4%) (Table 1, Supplementary table 1).

Overall, the most frequently assigned duty for research nurses was the administration of investigational medicinal products (IMP). When considering different study phases, research nurses were responsible for IMP administration in 81.1% (30/37) of countries in phase I trials, 86.5% (32/37 each) in phase II and III trials, 89.2% (33/37) in phase IV trials and 78.4% (29/37) in registry trials or observational studies. The second most common task was processing of blood samples, which was reported in 78.4% (29/37) of countries for phase I trials, 83.8% (31/37) for phase II trials, 81.1% (30/37) for phase III trials, 83.8% (31/37) for phase IV trials and 78.4% (29/37) for registry trials or observational

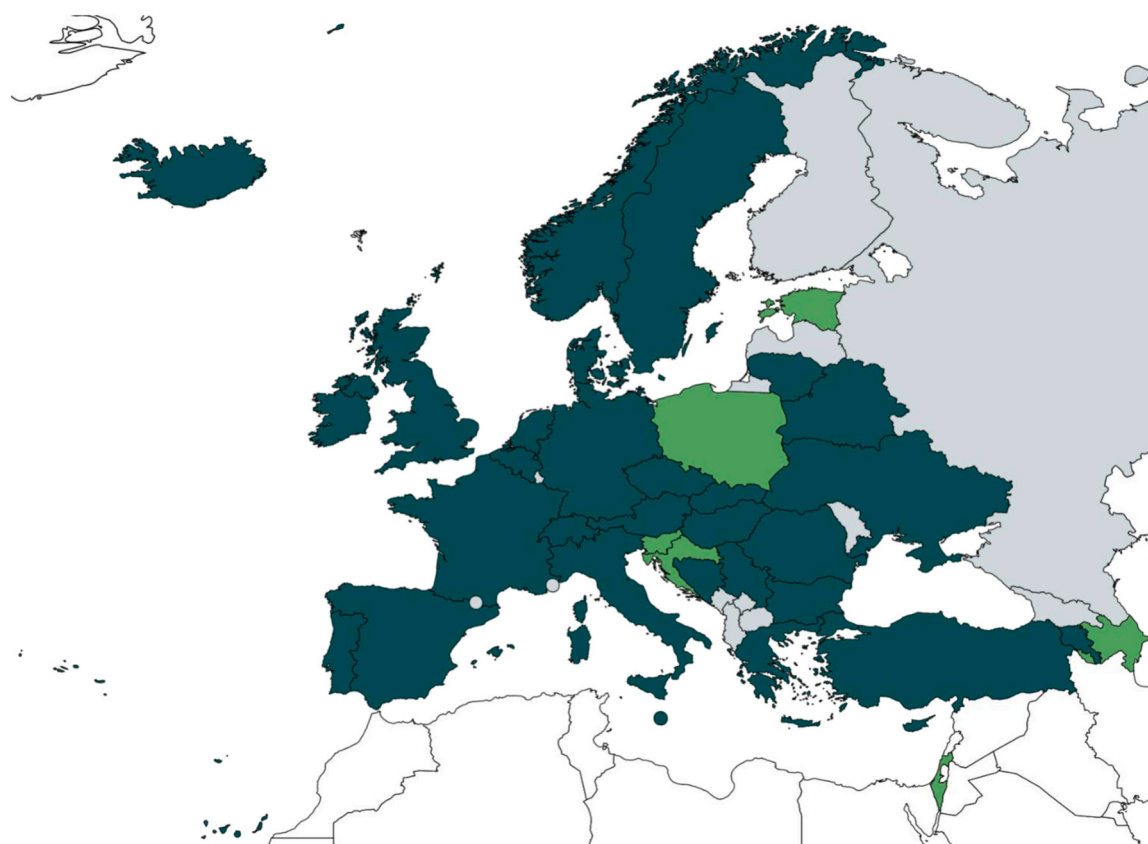


Fig. 1. Countries participating in the VACCCELERATE “How to become a Research Nurse?” survey. ● Countries with research nurse course locally available. ● Country with access to the VACCCELERATE Research Nurse online course. ● No data.

Table 1
Summary of requirements for becoming a research nurse in Europe.

Name for research nurse	n	%
Clinical research nurse	16	43.2%
Research assistant	4	10.8%
Research nurse	16	43.2%
Study assistant	5	13.5%
Study nurse	23	62.2%
Training necessary to become research nurse	37	100.0%
Nursing degree	32	86.5%
GCP course	30	81.1%
Renewal necessary	28	75.7%
Renewal not necessary	1	2.7%
Unknown whether renewal necessary	1	2.7%
Specific training	25	67.6%
Local providers of research nurse course	31	83.8%
Courses at hospital/site (internal training)	17	45.9%
Online courses	19	51.4%
Part of regular nurse studies	8	21.6%
University	17	45.9%
Workers union	2	5.4%
Courses run by other entities	20	54.1%
Study nurse certificate provided	25	67.6%
Research nurse training necessary to be renewed	15	40.5%
Responsibilities of a research nurse		
Phase I clinical trial		
Administration of IMP	30	81.1%
Patient training for new medicines/procedures	25	67.6%
Processing of blood samples	29	78.4%
Shipment of clinical samples	28	75.7%
Taking patient informed consent	17	45.9%
Phase II clinical trial		
Administration of IMP	32	86.5%
Patient training for new medicines/procedures	28	75.7%
Processing of blood samples	31	83.8%
Shipment of clinical samples	28	75.7%
Taking patient informed consent	17	45.9%
Phase III clinical trial		
Administration of IMP	32	86.5%
Patient training for new medicines/procedures	27	73.0%
Processing of blood samples	30	81.1%
Shipment of clinical samples	28	75.7%
Taking patient informed consent	19	51.4%
Phase IV clinical trial		
Administration of IMP	33	89.2%
Patient training for new medicines/procedures	29	78.4%
Processing of blood samples	31	83.8%
Shipment of clinical samples	29	78.4%
Taking patient informed consent	19	51.4%
Registry trials/Observational studies		
Administration of IMP	29	78.4%
Patient training for new medicines/procedures	28	75.7%
Processing of blood samples	29	78.4%
Shipment of clinical samples	27	73.0%
Taking patient informed consent	21	56.8%

GCP, good clinical practice; IMP, investigational medical product

studies. Additional tasks that were reported by more than 70% of countries included shipping clinical samples and providing patient training for new medicines or procedures (Table 1, Supplementary table 1).

4. Discussion

4.1. Overview of prerequisites for research nurses in Europe

The present survey provides an overview of the prevailing prerequisites for aspiring research nurses in Europe. The results indicate a similarity in requirements among the examined countries. Specifically, 86.5% of countries mandate a nursing degree, while 81.1% necessitate completion of a GCP course and 67.6% require supplementary specialised training. Research nurse courses are available through local

providers in 83.8% of countries, often in partnership with online organisations, universities, or hospitals. Primary responsibilities of research nurses encompass the administration of IMP, management of blood samples, coordination of sample shipments and provision of patient training.

4.2. Recognition of educational courses

The presence of specific educational courses for research nurses in most countries indicates a growing recognition of the importance of enhancing methodological procedures in clinical trials and observational studies (Moro-Tejedor and Garcia-Pozo, 2023; Samant et al., 2023; Adami and Kiger, 2005). However, it is noteworthy that the length of the research nurse education, as well as the providers of research nurse courses exhibited significant variation, ranging from workers' unions to individual institutions or hospitals (employers). This diversity in providers may be associated with differences in curriculum content, potentially leading to variations in the quality and comprehensiveness of the courses offered. However, despite the absence of specific courses for research nurses in only a few countries, all participating countries recognised the immense value and necessity of having such courses available. This collective acknowledgement highlights the importance placed on equipping research nurses with the specialised skills and knowledge required to effectively contribute to the research enterprise.

4.3. Mandatory nursing degrees and GCP courses

In 86.5% of the countries, it was mandatory for research nurses to have a nursing degree. The duration of a nurse's education varied between countries, ranging from 2 years in Belarus to 5 years in Albania and Armenia. However, when considering data from the European Union, where an integration process has taken place regarding higher education, the discrepancy narrows down to countries where it takes either 3 or 4 years to become a registered nurse (Cabrera and Zabalegui, 2021; Humar and Sansoni, 2017). It is important to note that not all countries consider nursing as a university bachelor degree, which may influence the baseline tasks assigned to nurses in different countries (Humar and Sansoni, 2017).

A completed GCP course was mandatory for research nurses in 30 out of 37 countries and in 28 out of 30 of those countries, it was required to renew the GCP accreditation regularly. This requirement demonstrates a commitment to maintaining up-to-date knowledge and continuously refreshing skills, thereby fostering the acquisition of new knowledge. The prevalence of online courses or courses conducted in research institutions indicates a strong need and interest in research nurse training. However, there is currently no official structure for such courses and a research nurse education in general at the European level. This suggests a gap in the provision of workshops and the implementation of a pan-European official initiative with a standardised curriculum could greatly improve the situation, not only for potential research nurses but also for clinical trial staff in general. Such an initiative would facilitate knowledge integration and equivalence across borders, enabling the transferability of knowledge to better research institutions. As a matter of fact, to overcome this limitation, the VACCELERATE Consortium (www.vacelerate.eu) (VACCELERATE, 2023) is offering, since January 2023, an organised online on-demand research nurse training programme through its VACCELERATE Academy (<https://vacelerate.eu/academy-2/>) (Sauthori et al., 2023) developed by experts in clinical research from Europe.

4.4. Variability in course offerings

Furthermore, the wide variety of organisations providing research nurse courses is evident, with significant variability in course durations. Courses can range from as short as one week in Norway to over two years in Malta, where it is recognised as a master's degree (L-Università,

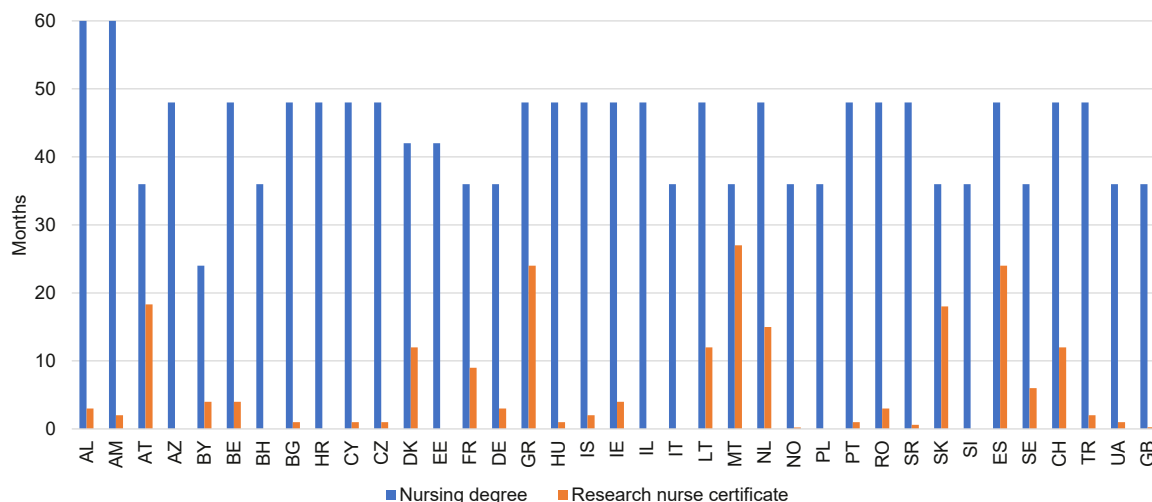


Fig. 2. Months necessary to obtain nursing degree and maximum months needed to become research nurse certificate per analysed country. **AL**, Albania; **AM**, Armenia; **AT**, Austria; **AZ**, Azerbaijan; **BE**, Belgium; **BG**, Bulgaria; **BH**, Bosnia and Herzegovina; **BY**, Belarus; **CH**, Switzerland; **CY**, Cyprus; **CZ**, Czechia; **DE**, Germany; **DK**, Denmark; **EE**, Estonia; **ES**, Spain; **FR**, France; **GB**, United Kingdom; **GR**, Greece; **HR**, Croatia; **HU**, Hungary; **IE**, Ireland; **IL**, Israel; **IS**, Iceland; **IT**, Italy; **LT**, Lithuania; **MT**, Malta; **NL**, Netherlands; **NO**, Norway; **PL**, Poland; **PT**, Portugal; **RO**, Romania; **SE**, Sweden; **SI**, Slovenia; **SK**, Slovakia; **SR**, Serbia; **TR**, Turkey; **UA**, Ukraine.

2023). This length different is significant enough to highlight the need for a more standardised and integrated curriculum, even among European Union member states. Developing an integrated curriculum would make the continent more attractive for clinical trial performance and enhance knowledge exchange and collaboration between institutions. Previous research has already emphasised the relevance of acquiring knowledge and experience for individuals pursuing careers in clinical research (Samant et al., 2023).

4.5. Task distribution and variability

The specific tasks assigned to research nurses exhibit significant variation across countries, similarly to the situation out of clinical trials (Maier and Aiken, 2016). Some tasks, such as the administration of IMP, processing of blood samples, shipment of clinical samples and patient training for new medicines/procedures, are widely prevalent among the analysed countries. The distribution of these tasks may be influenced by various factors, although no specific evidence was collected to determine the reasons behind it. One can speculate that the task distribution is likely driven by two main criteria. Firstly, the internal needs of the respective research institution, considering factors such as employee availability, acquired knowledge and experience and other institutional considerations (Maier and Aiken, 2016). Secondly, national regulations governing the scope of practice for nurses, as this may influence the range of tasks that research nurses are authorised to perform, a concern already mentioned in the literature (Nkrumah et al., 2018). Interestingly, there are no substantial differences observed in the distribution of research nurse tasks based on the phase of clinical trials or observational studies. This suggests that task allocation is not heavily influenced by the specific stage of research but rather by the aforementioned institutional and regulatory factors (Wit et al., 2023). Further investigation is needed to gain a more comprehensive understanding of the underlying factors driving task distribution variability and to explore potential opportunities for standardisation across countries.

4.6. Limitations

This manuscript has a few limitations that should be acknowledged. Firstly, it is important to note that not all countries were included in the study, resulting in some missing data. However, a significant proportion,

74% of the countries, with 81% of the continent population, (United Nations, 2023) did participate in the study, providing valuable insights. It is also important to consider that, with the exception of Russia, the non-participating countries generally have reduced populations. Additionally, due to the unavailability of the respective curricula, a detailed comparison of them was not possible. Unfortunately, we did not have the opportunity to investigate the reasons behind the exclusion of a nursing degree requirement for research nurses. As a result, we are unable to provide an elaboration on the differences and offer a contextual range for countries where a nursing degree is not required. This limits our ability to directly compare the content of the courses across countries. However, considering the diverse range of institutions and organisations involved in providing these courses, as well as the significant variations in the duration of the courses, it can be assumed that there is substantial heterogeneity in the course content in Europe. Finally, the use of the term nurse in the survey questions may have influenced the responses received. Participants who do not possess nurse education may not identify themselves as nurses and may not select the nurse-related options, despite performing similar tasks. Tasks such as patient recruitment and screening, data collection and management, participant education and consent, study coordination and administration, as well as quality assurance and regulatory compliance, are integral components of research activities. These tasks may be carried out by individuals with diverse backgrounds, including clinical research coordinators, data analysts, project managers, health educators and regulatory affairs specialists, among others.

5. Conclusions

In conclusion, this study provides valuable information on the current landscape of research nurse education and the tasks assigned to research nurses in European countries. Our findings highlight the need for harmonizing and standardizing training protocols for feasibility managers and site selection personnel is crucial for ensuring equitable access to clinical trials and bolstering the reliability of research outcomes. At the heart of this endeavour lies the necessity of mandating foundational training in GCP, ensuring that professionals involved in site feasibility assessments possess a thorough understanding of ethical principles, regulatory requirements and methodological standards fundamental to conducting rigorous and ethically sound research.

Achieving this goal demands collaborative engagement among government bodies, industry stakeholders, academic institutions and nursing regulatory entities to advocate for regulatory reforms. By recognizing the pivotal role played by feasibility managers and site selection personnel in shaping the trajectory of clinical research, stakeholders can influence the breadth of populations enrolled in trials and enhance the generalizability and applicability of research findings to diverse patient populations.

Facilitating access to comprehensive and standardized training programs aligned with nursing regulations and workforce requirements is paramount. This entails developing tailored training curricula integrating GCP principles with specialized nursing knowledge and competencies, equipping professionals with research methodology skills alongside a nuanced understanding of clinical practice dynamics, patient care considerations and ethical imperatives specific to their field. Through strategic collaborations and concerted advocacy efforts, stakeholders can dismantle barriers to standardized training, address resource constraints and foster a culture of continuous learning within the realm of clinical research, ultimately advancing inclusivity, research quality and patient outcomes worldwide. Finally, the study highlights the necessity for strategic actions aimed at attracting and inspiring prospective nurses to pursue research-oriented paths, thereby advancing the scientific community.

Ethics approval

Not applicable. This survey was performed as part of our routine surveillance.

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CRediT authorship contribution statement

Fiona A. Stewart: Conceptualization, Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Jon Salmanton-García:** Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization, Visualization, Writing – original draft, Writing – review & editing. **Sanne H. I. Hofstraat:** Conceptualization, Methodology, Writing – review & editing. **Pauline Wipfler:** Conceptualization, Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Oliver A. Cornely:** Funding acquisition, Resources, Writing – review & editing. **Patricia Bruijning-Verhagen:** Conceptualization, Methodology, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.nepr.2024.103953](https://doi.org/10.1016/j.nepr.2024.103953).

References

- Adami, M.F., Kiger, A., 2005. A study of continuing nurse education in Malta: the importance of national context. *Nurse Educ. Today* 25 (1), 78–84.
- Amicucci, M., Dall'Oglio, I., Biagioli, V., et al., 2022. Participation of nurses and allied health professionals in research activities: a survey in an academic tertiary pediatric hospital. *BMC Nurs.* 21 (1), 159.
- Ballantine, A., Potter, R., 2023. What are the experiences of nurses delivering research studies in primary care? *Prim. Health Care Res. Dev.* 24, e46.
- Cabrera, E., Zabalegui, A., 2021. Bologna process in European nursing education. Ten years later, lights and shadows. *J. Adv. Nurs.* 77 (3), 1102–1104.
- Chen, Q., Li, Z., Tang, S., et al., 2022. Development of a blended emergent research training program for clinical nurses (part 1). *BMC Nurs.* 21 (1), 2.
- Grady, C., Edgerly, M., 2009. Science, technology and innovation: nursing responsibilities in clinical research. *Nurs. Clin. North Am.* 44 (4), 471–481.
- Humar, L., Sansoni, J., 2017. Bologna process and basic nursing education in 21 European countries. *Ann. Ig.* 29 (6), 561–571.
- King, O., West, E., Lee, S., et al., 2022. Research education and training for nurses and allied health professionals: a systematic scoping review. *BMC Med Educ.* 22 (1), 385.
- VACCELERATE Academy <https://vaccelerate.eu/academy-2/> (Last accessed July 04, 2023). 2023.
- L-Università ta' Malta. Postgraduate. Nursing (<https://www.um.edu.mt/courses/keyw ord/Postgraduate/Nursing>) (Last accessed July 03, 2023). 2023.
- Maier, C.B., Aiken, L.H., 2016. Task shifting from physicians to nurses in primary care in 39 countries: a cross-country comparative study. *Eur. J. Public Health* 26 (6), 927–934.
- Moro-Tejedor, M.N., Garcia-Pozo, A., 2023. Role of the nurse in research. *Rev. Esp. Salud Pública* 97.
- Nkrumah, I., Atuhaire, C., Priebe, G., Cumber, S.N., 2018. Barriers for nurses' participation in and utilisation of clinical research in three hospitals within the Kumasi Metropolis, Ghana. *Pan Afr. Med. J.* 30, 24.
- Salmanton-García, J., Busca, A., Cornely, O.A., et al., 2021. EPICOVIDEHA: a ready to use platform for epidemiological studies in hematological patients with COVID-19. *Hemasphere* 5 (7), e612.
- Salmanton-García, J., Stewart, F.A., Heringer, S., et al., 2022. VACCELERATE volunteer registry: a European study participant database to facilitate clinical trial enrolment. *Vaccine* 40 (31), 4090–4097.
- Salmanton-García, J., Wipfler, P., Valle-Simon, P., et al., 2023. VACCELERATE site network: real-time definition of clinical study capacity in Europe. *Vaccine* 41 (26), 3915–3922.
- Samant, A.N., Fanelli, J.E., Khanna, A.K., Segal, S., 2023. A successful gap-year clinical research technician (CRT) program at an academic anesthesiology department. *Cureus* 15 (5), e39000.

United Nations, Department of Economic and Social Affairs, Population Division. World Population Prospects 2022 (<https://population.un.org/wpp/>) (Last accessed July 04, 2023). 2023.

VACCELERATE Consortium (<https://vaccelerate.eu>) (Last accessed July 04, 2023). 2023.

Viberg Johansson, J., Bentzen, H.B., Mascalzoni, D., 2022. What ethical approaches are used by scientists when sharing health data? An interview study. *BMC Med. Ethics* 23 (1), 41.

Wit, R.F., de Veer, A.J.E., Batenburg, R.S., Francke, A.L., 2023. International comparison of professional competency frameworks for nurses: a document analysis. *BMC Nurs.* 22 (1), 343.