Original Paper

Consensus on Core Competencies of Undergraduate Life Sciences Students for Entry-Level Participation in Clinical Trials: RAND-Modified Delphi Study

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Abstract

Background: The competencies required of life sciences graduates to participate in clinical trial research teams are poorly defined.

Objective: This study aimed to establish a structured consensus on the core competencies that students must acquire during their degree programs.

Methods: A RAND-modified Delphi procedure was conducted using 2 rounds of online questionnaires, a virtual meeting, and a final review. The process began with a questionnaire completed by experts from the University of Córdoba and the Maimonides Institute for Biomedical Research of Córdoba (3 principal investigators, 1 study coordinator, and 1 data manager). The 48 competencies initially proposed were reviewed by a panel of 18 experts representing 6 clinical research groups from universities and biomedical research institutes in Andalusia, Spain. The relevance of each proposed competency was rated on a 9-point Likert scale. Competencies were accepted if they achieved a mean score of 7 points or higher and at least 70% of ratings in the top tertile (scores of 7-9).

Results: The 18 experts achieved 100% consensus on a panel of 48 competencies organized into 3 sections: fundamental concepts (n=23, 47.9% of the competencies), clinical trial development (n=23, 47.9% of the competencies), and certifications (n=2, 4.2% of the competencies).

Conclusions: This consensus defines the core competencies required of undergraduate life sciences students for entry-level participation in clinical trial research. It also provides a framework for designing training strategies in both undergraduate and graduate programs of study.

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KEYWORDS

clinical research; clinical trials as topic; competency-based education; Delphi technique; undergraduate education; life sciences education

Introduction

Clinical trials [1] are a cornerstone of human clinical research and are often performed to evaluate the efficacy and safety of new pharmaceutical drugs. Many hospitals have dedicated clinical research teams that conduct both registrational clinical trials sponsored by the pharmaceutical industry and "academic" trials led by scientific institutions.

The design and implementation of a clinical trial is a highly complex process involving a diverse team of professionals, typically life sciences graduates [2-4] (Table 1). Protocols must be submitted for evaluation and approval by health authorities such as the Spanish Agency for Medicines and Medical Devices under the Ministry of Health, Social Services, and Equality in Spain [5], as well as by research ethics committees [6,7]. Once approval is granted, trials are highly demanding as they require strict adherence not only to the protocol guidelines but also to rigorous ethical and legal standards established internationally and regulated nationally. Depending on their level of responsibility, each investigator on the team is expected to possess different levels of competency. However, the specific competencies (ie, knowledge, skills, and attitudes) that should be attained during undergraduate life sciences programs are poorly defined. In fact, there is little consensus regarding these general and basic competencies at the undergraduate level despite the emphasis often placed on translational clinical research [8]. Moreover, many life sciences graduates do not perceive clinical research as a potential area for professional development.

In this context, it is argued that competency-based educational frameworks are not static lists of skills but dynamic constructs developed and applied within complex professional environments. Professional expertise is increasingly understood as the integration of cognitive, technical, and nontechnical skills, including context-dependent decision-making [9-11]. From this perspective, competency development can be viewed as a progressive process that begins during undergraduate training and continues through postgraduate education and professional practice. Early exposure to these competencies may facilitate their integration into more complex, context-dependent performance, including the development of higher-order reasoning skills [12]. Importantly, this early exposure does not imply full mastery but rather the acquisition of foundational components that can be further developed in later stages of training. However, many undergraduate curricula in the life sciences do not systematically address these competencies, potentially limiting graduates' integration into multidisciplinary clinical research teams. In this context, competency-based models in medical education support the introduction of foundational competencies at the undergraduate level, which can be progressively developed across subsequent stages of training [8,13]. This approach is particularly relevant in clinical research, where multidisciplinary teams include professionals with diverse backgrounds, such as clinicians, study coordinators, data managers, or methodologists, who require a shared baseline of competencies to collaborate effectively. Furthermore, fostering early engagement in research among physicians and nurses may contribute to the development of clinician investigators and other research-oriented profiles while allowing for progressive specialization in line with individual career choices. Previous work has also shown that undergraduate curricula may provide exposure to foundational knowledge and skills, whereas applied domains requiring clinical judgment, critical appraisal, and decision-making often remain insufficiently developed, particularly in areas such as antimicrobial use and therapeutic decision-making [14].

These findings support the need for structured competency frameworks in clinical research. To this end, this study sought to establish a consensus on the core competencies required for participation in clinical trial research using a RAND-modified Delphi procedure [15,16]. This methodology has been previously validated for defining competencies based on expert opinion [8,17].

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Table 1. Definitions.

Term	Definition
General competencies	Basic standards that an investigator must achieve depending on their training and level of responsibility; does not include discipline-specific competencies
Scientific knowledge	An organized body of knowledge obtained through scientific methods, including systematic observation and empirically testable hypotheses
Life sciences graduates	Individuals with undergraduate training in health and biological sciences (eg, medicine, nursing, pharmacy, biology, and biochemistry) who may participate in clinical research teams
Skill	The ability to perform a task correctly and efficiently
Attitude	A learned predisposition to respond consistently to a given object or situation
Clinical trial	A medical research study involving human participants
Academic clinical trial	A clinical trial funded by public or academic institutions to generate scientific knowledge
Commercial clinical trial	A clinical trial funded by industry for commercial and research purposes
Research ethics committee	A body responsible for the ethical review and oversight of research protocols
Protocol	A document describing the design, methodology, and organization of a clinical trial
Informed consent	A document that provides participants with information about a clinical trial, including risks and benefits, and requires signed agreement
GCP[a] certificate	A certification attesting to knowledge of GCP standards for conducting clinical trials
IATA[b] certificate	A certification for the safe handling and shipment of biological samples in accordance with IATA regulations
PI[c]	The individual responsible for conducting a clinical trial at a research site
Study coordinator	A professional responsible for coordinating and managing clinical trial activities
Data manager	A professional responsible for clinical data management and quality control
Clinical trial database	A structured dataset containing data collected from participants during a clinical trial
CRO[d]	A company contracted by the sponsor to manage and monitor clinical trials

[a]GCP: good clinical practice.

[b]IATA: International Air Transport Association.

[c]PI: principal investigator.

[d]CRO: contact research organization.

Methods

Study Design

We conducted a RAND-modified Delphi procedure [15-20] to establish consensus on the general and basic competencies that undergraduate life sciences students must acquire to participate in clinical trial research teams (see the key definitions in Multimedia Appendix 1). The consensus was developed between June 2024 and December 2024 and consisted of four stages: (1) a first round of questionnaires, (2) a virtual meeting of a panel of experts, (3) a second round of questionnaires, and (4) a final review. Depending on participant availability, the rounds of questionnaires were conducted online or via email by means of a survey. The data were analyzed using Microsoft Excel. Examples of the questionnaires are provided in Multimedia Appendix 1. The competencies were defined with a focus on foundational knowledge and awareness appropriate for entry-level participation in clinical trial investigation rather than on full performance of role-specific responsibilities. Additionally, they were structured across three predefined levels: (1) foundational (basic knowledge and understanding of key concepts), (2) intermediate (ability to apply knowledge under supervision in practical settings), and (3) advanced (capacity to perform tasks independently and make informed decisions within the context of clinical research).

Selection of the Panel of Experts

Six research groups from universities and biomedical research institutes in Andalusia, Spain, were selected for the study. Participants were invited through a 2-stage process. In the first stage, principal investigators (PIs) who were experts in the field, clinical investigators, and professors were identified at each institution. Each expert was then asked to invite 2 additional participants with more than 5 years of experience, ideally resulting in a panel of 18 experts comprising 6 clinical investigators with teaching experience, 6 data managers, and 6 clinical trial coordinators. Teleconferences were held with each group to ensure that all panel members had a similar understanding of the study objectives, definitions (Multimedia Appendix 1), and procedures. The panel members were asked to share any insights based on their own experiences. Additionally, all participants were provided with supporting documentation to standardize their understanding of competencies. The material was derived from content already included in the syllabus of the elective undergraduate medical

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course Clinical Trials and Good Clinical Practice coordinated by AC and JT-C [21].

First Round of Questionnaires

The questionnaire was designed by a working group of 5 members from the University of Córdoba and Maimonides Institute for Biomedical Research of Córdoba: 3 clinical trial PIs, 1 study coordinator, and 1 data manager. After reviewing the literature, 48 competencies were selected and divided into three blocks: (1) fundamental concepts (n=23, 47.9% of the competencies), (2) clinical trial development (n=23, 47.9% of the competencies), and (3) certifications (n=2, 4.2% of the competencies). A 9-point Likert scale [22] ranging from 1 (not at all important) to 9 (critically important) was used consistently across all rounds.

Consensus was defined via a multistep process. In the first round, competencies were accepted if they achieved a mean score of 7 or higher and at least 70% of ratings in the top tertile (scores of 7-9). Competencies with a mean score of 7 points or higher but with less than 70% of scores in the top tertile were discussed at the expert panel meeting. Agreement was reached through structured discussion, aiming for at least 80% consensus among participants. Competencies with a mean score of less than 7 were not included.

Respondents could provide comments on each competency, including suggestions for rewording or removing items as well as proposals for including other competencies.

Expert Panel Roundtable Discussion

The expert panel received a report detailing the overall scores for each competency assessed in the first round. A virtual roundtable session moderated by AC from the leadership group was then held. The objectives of this session were to (1) present the results of the first round, (2) review competencies for which agreement had not been reached, and (3) discuss whether newly suggested competencies should be included for evaluation by all members of the expert panel in the second round. Discussions continued until 80% consensus was reached among the participants.

Second Round of Questionnaires

In the second round, the expert panel completed a questionnaire that consisted of (1) providing feedback on the decisions made during the roundtable session, (2) assessing the relevance of newly suggested competencies using the Likert scale, and (3) evaluating the revised wording of the modified competencies.

Final Review

The selected competencies were subsequently circulated to the expert panel for final review and confirmation, resulting in unanimous agreement among all members.

Ethical Considerations

According to Spanish Law 14/2007 on Biomedical Research [23], this study did not require approval from an institutional review board or ethics committee as it did not involve patients, clinical data, or identifiable personal information. The research was based on a consensus process involving expert participants and focused on professional opinions rather than personal or sensitive data. Participation was voluntary, and completion of the questionnaires was considered implied consent. No identifiable information was collected or stored. Therefore, in accordance with applicable regulations and institutional policies, formal ethics approval was not required. No financial compensation was provided for participation.

Results

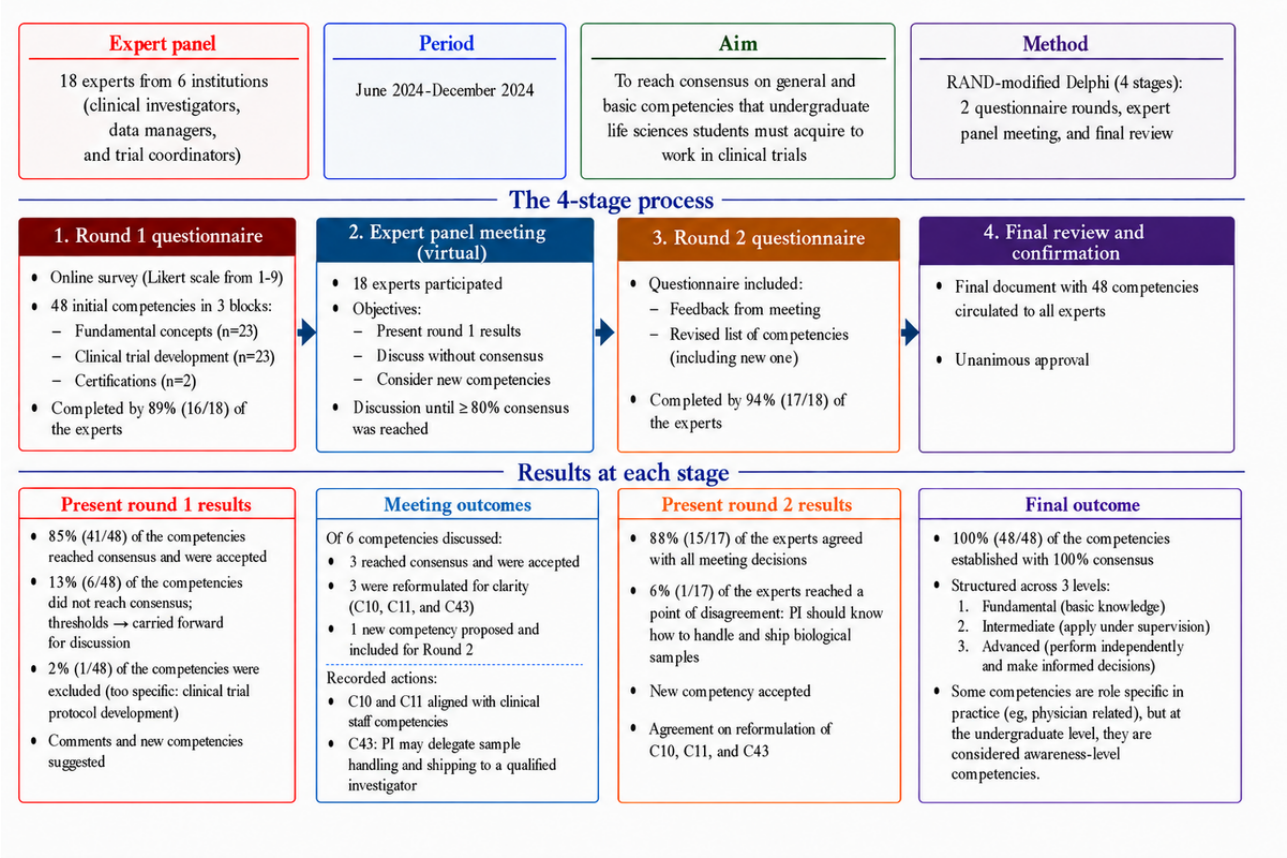
First Round of Questionnaires

The first-round questionnaire was completed by 88.9% (16/18) of the investigators invited to participate. In the first round, consensus was reached on 85.4% (41/48) of the competencies, whereas there was disagreement on a total of 12.5% (6/48) because they did not meet the consensus thresholds in round 1 and were therefore carried forward for discussion during the expert panel meeting. Only 2.1% (1/48) of the competencies, which were related to the development of a clinical trial protocol (section 2, point 1.2 in Multimedia Appendix 1), were excluded because they were considered too specific.

A description of the 18 experts who participated in the consultation is available in Multimedia Appendix 2. Item-level results for all competencies across Delphi rounds are provided in Multimedia Appendix 3. Figure 1 summarizes the results of the 2 questionnaires, the virtual meeting, and the final consensus review.

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Figure 1. Overview of the RAND-modified Delphi process and study results. PI: principal investigator.



Expert Panel Roundtable Discussion

All 18 members of the expert panel attended the virtual meeting. Of the 6 competencies discussed, consensus was reached on 3. The remaining 3 competencies (C10, C11, and C43) were reformulated to improve clarity and preserve their original meaning and subsequently included in the second Delphi round. In addition, 1 new competency was proposed during the expert panel discussion and was later accepted after reaching consensus. The reformulation of competencies C10 and C11 consisted of explicitly aligning them with competencies specific to clinical staff. For C43, it was proposed that the PI could delegate the handling and shipping of samples to another qualified investigator, meaning that the PI would not need to perform these tasks personally.

Second Round of Questionnaires

A total of 94.4% (17/18) of the panel members completed the second round of questionnaires. Of these panel members, 88.2% (15/17) stated that they agreed with all the decisions made at the expert panel meeting. The only point of disagreement was that the PI should know how to handle and ship biological samples.

The newly proposed competency was accepted. Agreement was also reached on reformulating the 3 competencies that had been previously modified in the virtual meeting.

Final Review

On the basis of feedback obtained in the second round, a final document outlining 48 competencies was drawn up. The final consensus document (Table 2) was sent to the expert panel and received unanimous approval from all members (18/18, 100%). The extended version of the final competency document is provided in Multimedia Appendix 4.

Some competencies identified in the consensus process are traditionally associated with specific professional roles (eg, physician-related tasks). However, these are interpreted as awareness-level competencies rather than expected performance within the context of undergraduate training. Specifically, we considered that all competencies could be developed across the 3 defined levels (foundational, intermediate, and advanced), although competencies C10, C11, and C12 were considered specific to physicians. The final set of competencies reflects the outcome of a multistage consensus process combining quantitative ratings, expert discussion, and final validation.

The identified competencies can be grouped into higher-order domains reflecting different dimensions of clinical investigation practice, including foundational knowledge, clinical and decision-making skills, research governance, trial management, and transversal competencies such as teamwork and communication. This structure highlights the multidimensional nature of clinical investigation competency by integrating theoretical, practical, and contextual elements into a coherent framework.

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Table 2. Consensus on core competencies for life sciences graduates participating in clinical trials.

Section	Competency	Code
Fundamental concepts—clinical research	Principles, scope, types, and phases of clinical research and clinical trials, including legal, ethical, and economic aspects	C1-C9
Clinical method (physicians)	Clinical assessment, prescription of investigational drugs, and evaluation of adverse events	C10-C12
Basic biostatistics	Interpretation of cohorts, variables, and clinical outcomes (mortality, cure, efficacy, and safety), including pharmacokinetics	C13-C19
Teamwork	Identification of team roles, coordinated care, and application of ethical and equality principles	C20-C23
Research design	Formulation of the research question, hypothesis, and study objectives	C24
Trial responsibilities	Understanding sponsor and principal investigator responsibilities under GCP[a]	C25-C26
Ethics and governance	Ethics committee processes and regulatory documentation	C27-C28
Trial management	Clinical trial contract, financial aspects, and protocol structure and implementation	C29-C33
Informed consent	Structure, process, and involved parties	C34-C36
Data and documentation	Source documents and data integrity	C37-C38
Trial procedures	Site initiation, closeout, safety reporting, biological samples, monitoring, and audits	C39-C45
Publication	Compliance with CONSORT[b] reporting standards	C46
Certifications	GCP and IATA[c] certification	C47-C48

[a]GCP: good clinical practice.

[b]CONSORT: Consolidated Standards of Reporting Trials.

[c]IATA: International Air Transport Association.

Discussion

Principal Findings

This study established a consensus-based framework of 48 core competencies for undergraduate life sciences students involved in clinical trial research. Consensus (100% agreement) was achieved among a multidisciplinary panel of experts using a RAND-modified Delphi process. The competencies were organized into three main domains: (1) fundamental concepts, (2) clinical trial development, and (3) certifications. All of them can be interpreted across progressive levels of learning (foundational, intermediate, and advanced). These findings support the view of competencies as integrated and progressively developed capacities rather than isolated skills, thus reinforcing existing competency-based education models.

The competencies also involve higher-order cognitive processes such as critical appraisal and decision-making in complex clinical contexts [12]. In this study, these dimensions are reflected in the competencies identified through the Delphi process, which incorporate both procedural and analytical components.

In addition, clinical research competency involves an epistemic dimension related to how individuals understand, evaluate, and construct knowledge. This dimension is embedded across multiple competencies, including those related to biostatistics (C13-C19) and protocol interpretation (C31-C33), which require the ability to assess the validity and applicability of evidence. Similarly, competencies addressing adverse events (C41 and C42) and clinical decision-making processes (C10-C12) involve judgment under uncertainty. Overall, competency development can be understood as a progression from basic knowledge toward increasingly autonomous and reflective engagement with evidence, consistent with models of epistemic cognition [9].

Comparison With the Literature

It is widely recognized that there is a shortage of professionals trained in human clinical research. Training in this field should begin at the undergraduate level, not only in medicine and nursing but across all life sciences degree programs. Our study addressed this gap by providing a structured, consensus-based competency framework tailored to undergraduate training. Although there is extensive literature describing the competencies required for clinical research professionals and numerous postgraduate programs where advanced competencies can be acquired [24], these frameworks have not been specifically designed for undergraduate education.

Among the most widely recognized competency frameworks [17,24,25] is the one defined by the Joint Task Force for Clinical Trial Competency, which comprises 10 domains and 47 competencies [24]. This framework, validated in 2018, has been widely applied in postgraduate training programs but has not been specifically validated for undergraduate education. More recently, Mendell et al [17] proposed a framework consisting of 59 competencies across 3 levels (fundamental, skilled, and advanced). In our study, we developed a consensus document that defines a set of competencies that all investigators involved in the development of clinical trials should acquire, with the aim of standardizing undergraduate training.

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Implications

Although some competencies identified in the consensus process are traditionally associated with specific professional roles (eg, physicians or PIs), these should be interpreted at an introductory level within undergraduate education. Their inclusion reflects the need for early exposure to and understanding of clinical trial processes rather than the expectation of independent performance. Even at an introductory level, participants benefit from a broad understanding of the operational, ethical, and regulatory dimensions of clinical research. From an educational perspective, the competencies identified in this study can be interpreted across different levels of progression (foundational, intermediate, and advanced). This classification is not derived from the Delphi process itself; rather, it is proposed as an interpretative framework to facilitate the integration of these competencies into undergraduate and postgraduate training pathways. More specifically, they aim to promote understanding of the fundamental principles of bioethics and clinical research while providing training in the design, development, and analysis of clinical trial results across all phases.

Importantly, some competencies required reformulation during the consensus process, highlighting the complexity of aligning general research competencies with role-specific clinical responsibilities. This was particularly relevant for competencies initially defined in broader terms, which were subsequently refined to better distinguish between general research competencies and those requiring clinical expertise.

We used a RAND-modified Delphi method [19,20] based on questionnaires. The use of a multistep consensus process combining quantitative thresholds and qualitative discussion is consistent with the established RAND-modified Delphi methodology. The Delphi group included investigators with varying levels of competency. This allowed us to avoid the potential bias that can be introduced when only including investigators with advanced skills due to differences in performance based on their competency level [26]. The competencies are presented in 3 sections. The first section focuses on the acquisition of competencies in general clinical research knowledge. The second section refers to the acquisition of competencies that enable investigators to participate in the design and development of clinical trials. The third section provides the certification required for participation in clinical trials. Of the proposed competencies, only 1 did not obtain the score established for acceptance (section 2, competency 1.2 included in Multimedia Appendix 1). The expert panel concluded that specific and qualified training was required to acquire this competency.

A consistent methodology was used in this study. To ensure that the members of the expert panel fully understood the proposed competencies, all concepts were defined in a consultation document (Table 1). The study objectives, the evaluation system for scoring each competency, and the process leading to the final competency document were explained to all participants. The level of satisfaction (100%) with the final set of competencies was high (100%). This may have been because the members of the expert panel were able to comment on all the proposals via teleconference (face-to-face) or email and because a final round was held to ensure greater consistency across the entire set of competencies.

Any process for acquiring competencies must be evaluated. However, there is no validated system for evaluating these competencies. At advanced levels, competency is often evaluated through scientific output (bibliometric measures), but this approach is not suitable for undergraduate or graduate programs. Experts agree that such evaluations should combine both objective measures and subjective assessment (self-evaluation) of competency levels before and after each acquisition process. Consequently, there is a clear need to develop an evaluation program for the competencies defined in this document.

The competencies outlined in this document could be used by official bodies, such as universities, to establish a standardized training framework [27]. They could also form part of undergraduate programs for students in fields such as medicine or nursing [28] who may be members of clinical trial research teams. However, it should be noted that graduates from other life sciences disciplines also participate in clinical research. The relevance of integrating these competencies into their undergraduate curricula should therefore be carefully evaluated.

Postgraduate programs could also integrate these competencies into their curricula to standardize skill acquisition among research professionals [18]. Additionally, the competencies could serve as a tool for companies to assess the qualifications of professionals involved in clinical trial monitoring [29]. Achieving this, however, would require clearly defining the skills expected of each investigator according to their specific responsibilities within the trial.

The competencies identified in this study extend beyond technical knowledge and reflect key elements of clinical practice in research settings. Competencies such as teamwork, communication, ethical decision-making, and data interpretation are closely linked to core human factors domains, including situational awareness and error prevention. In this context, the proposed framework integrates a human factors perspective and supports not only knowledge acquisition but also the development of nontechnical skills essential for safe and effective participation in clinical research teams.

Limitations

This study has several limitations that should be acknowledged. First, the expert panel comprised 18 participants from a single geographic region in southern Spain (Andalusia), which may limit the generalizability of the findings to other educational or health care contexts. Although the panel included a multidisciplinary group of professionals with diverse roles in clinical research (PIs, study coordinators, and data managers), the consensus reflects a region-specific perspective shaped by local institutional structures, regulatory frameworks, and training pathways. Therefore, caution should be exercised when extrapolating these findings to other national or international settings. Future studies should aim to validate and refine this competency framework in broader, more heterogeneous populations, including experts from different countries, health systems, and academic environments, to enhance its external

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validity and global applicability. To minimize potential selection bias inherent in this type of study and improve the relevance of the analysis, the expert panel included clinical investigators with teaching experience as well as a multidisciplinary team of pharmacists, nurses, and biologists engaged in research (Multimedia Appendix 2). In addition, consensus-based approaches such as the Delphi method inherently involve an interpretive component as agreement among experts reflects shared perspectives rather than objective truth. Despite these efforts, the selection process may still have introduced selection bias related to professional background and regional context.

Conclusions

This consensus defines the core competencies that undergraduate life sciences students must acquire for entry-level participation in clinical trial research. It also provides a framework for designing training strategies in both undergraduate and graduate programs of study. The competencies defined in this study should be considered preliminary and will therefore require further validation in broader and more heterogeneous settings before being generalized at the national or international level. Following such validation, this framework may inform the design of undergraduate biomedical curricula aimed at preparing graduates for entry-level participation in clinical research teams.

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Data Availability

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study. Questionnaire responses and consensus data were collected during the Delphi process and are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C
Data curation: AC, JT-C
Investigation: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C
Methodology: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C
Validation: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C
Visualization: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C
Writing—original draft: AC, JT-C
Writing—review and editing: AC, PC-P, JJC, DC-M, RB-O, EV-M, JP-C, CA-V, IM, JT-C

Conflicts of Interest

AC receives overarching funding for research from the area of infectious diseases of the Centro de Investigación Biomédica en Red (21/13/00012). JJC received research grants from Pfizer and Menarini and honoraria for training activities from Pfizer, Merck, Shionogi, and Menarini. JT-C has served as scientific advisor for Pfizer, MSD, Shionogi, Advanz, and Menarini; has collaborated in educational activities for Pfizer, MSD, and Shionogi; and has received research grants from MSD and Menarini. All other authors declare no conflicts of interest.

Multimedia Appendix 1

Delphi questionnaire used in round 1.
[DOCX File , 48 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Characteristics of the expert panel.
[DOCX File , 16 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Item-level results across Delphi rounds.
[DOCX File , 19 KB-Multimedia Appendix 3]

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Multimedia Appendix 4

Consensus on core competencies for life sciences graduates participating in clinical trials (extended version).
[DOCX File , 19 KB-Multimedia Appendix 4]

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Abbreviations

PI: principal investigator

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