

criteria but could not be retrieved after several efforts were excluded. Studies from updated searches are pending assessment. Agreement between reviewers was 86%. Preliminary results included 982 systematic reviews. There are several drawbacks in assessing compliance with PRISMA 2009 guidelines in leading Rheumatology journals. Some studies even fail to specify in any part of the manuscript whether they intended or not to comply with PRISMA or any other guideline. This is necessary to assess compliance with PRISMA since authors may have chosen to adhere to other guideline (such as the Cochrane Handbook for Systematic Reviews of Interventions, the JBI Manual of Evidence Synthesis, etc). Additionally, some studies mention PRISMA compliance without specifying the consulted version. This was not necessary before 2020 but it is nowadays, since the new version of PRISMA incorporates some changes compared to its previous version. These changes involve the recommendations for reporting the search strategies. It is worth noting that the original version of PRISMA is still used in systematic reviews published after 2020. Certain studies include only a PRISMA flow diagram or cite PRISMA 2009 in their references, making difficult to determine if they were committed to comply with the full guideline. Others cite PRISMA extensions (e.g., PRISMA-P) solely within their references which is also inconclusive.

Conclusion: Assessing systematic reviews that adhere to PRISMA is challenging due to heterogeneous reporting practices. Clear statements of PRISMA usage and improved understanding of its flow diagram and extensions are needed to increase methodological rigor and transparency. Evidence synthesists should be aware of the importance of correctly applying PRISMA and reporting it accordingly.

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Acknowledgements: NIL.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2025-eular.C40

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ABS1224-HPR A CALL FOR A COMPREHENSIVE ROLE DEFINITION OF THE STUDY COORDINATOR IN RHEUMATOLOGICAL CLINICAL STUDIES

Keywords: Education, Clinical Trial, Systematic review

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Background: The rapid and constant evolution of clinical studies in rheumatology requires the work of many professionals in addition to the physicians and/or researchers directly involved, from the design and planning phases to the execution. Study coordinators are in charge of operational management of clinical studies and ensure that collected data are accurate and ready for the purposes of the studies within private or public research institutions. Their contributions bridge the gap between patient care and regulatory compliance, which can ultimately lead to better clinical outcomes. The expertise of Study Coordinators is particularly needed in academic settings where studies may be subject to strict budgeting and securing funding can be highly challenging. Moreover, in said settings, research often has a dual mission of advancing scientific knowledge and educating the next generation of researchers, Study Coordinators are therefore instrumental in facilitating collaborations between principal investigators, funding bodies, and other stakeholders.

Objectives: The literature offers a somewhat fragmented, often contradictory descriptions of the role of Study Coordinators, frequently overlapping with that

of Clinical Data Manager or Clinical Research Coordinators. Larger teams would benefit from a more defined task assignment in order to conduct more complex or multi-center studies, also in the field of rheumatic diseases. These professionals are often described synonymously due to the inadequate definition of their roles and responsibilities. The latter may be particularly critical in a number of countries where legal recognition is still not well defined. Clinical studies often span multiple countries and involve teams with different cultural and regulatory backgrounds: a harmonisation of roles on an international level therefore could be advantageous and initiate a standardisation of practices and expectations, and supporting multinational teams and cross-border studies. A stratification proposal of the roles and a list of the main tasks for integrating into comprehensive guidelines would help navigating the challenges specific to studies investigating rheumatic diseases

Methods: A systematic review was conducted to examine international literature on the subject, focusing on legal frameworks, policies and regulations. Databases such as PubMed the NIH, and NIHR were utilised to identify relevant articles and definitions. Additionally, institutional websites from key national and international sources (e.g., congress.gov, eur-lex.europa.eu, legislation.gov.uk, WHO) were accessed to retrieve official laws and regulations.

Results: An accurate analysis of the literature and websites reveals three main professional roles: Clinical Data Manager, clinical research coordinators and Study Coordinators; however the definition, roles and responsibilities of these professionals are not sufficiently defined and vary considerably across different international settings. Therefore, a rational proposal of stratification, to focus on the near future should contemplate the following roles and activities: i. the Clinical Data Manager focuses on the statistical and analytical aspects, ensuring the integrity and accuracy of data, ii. the Clinical Research Coordinator oversees the medical staff and patient care, ensuring ethical standards and participant safety; finally iii. the Study Coordinator is responsible for managing the administrative and regulatory tasks, ensuring adherence to protocols and complying with industry regulations (see Table 1).

Table 1

Role	Description	Requirements	Key Roles
Clinical Data Manager	Focuses on the statistical and analytical aspects of clinical studies, ensuring the integrity, accuracy, and reliability of the data collected.	<ul style="list-style-type: none"> - Strong background in statistics and data analysis. - Expertise in clinical trial data management tools and software. 	<ul style="list-style-type: none"> - Oversee data collection, validation, and analysis. - Ensure data accuracy, consistency, and integrity. - Prepare data reports for regulatory submission.
Clinical Research Coordinator	Supervises medical staff and manages patient recruitment, enrollment, and care throughout the clinical trial. Ensures that patients receive appropriate care and attention.	<ul style="list-style-type: none"> - Medical or healthcare-related background (e.g., nursing, medicine). - Experience in patient management and trial protocols. - Good communication and organizational skills. 	<ul style="list-style-type: none"> - Oversee patient recruitment and care. - Supervise medical staff and ensure adherence to protocols. - Ensure participant safety and informed consent.
Study Coordinator	Manages the administrative and regulatory aspects of clinical studies, ensuring compliance with study protocols and regulatory requirements. They serve as active links between medical, administrative, and analytical teams to ensure the trial's success.	<ul style="list-style-type: none"> - Strong organisational and administrative skills. - Knowledge of regulatory guidelines (e.g., FDA, EMA). - Experience in managing clinical trial documentation. 	<ul style="list-style-type: none"> - Coordinate regulatory submissions and approvals. - Ensure compliance with regulatory and ethical guidelines. - Manage study documentation and trial logistics.

Conclusion: Such a reorganisation of various positions may highlight the critical importance of the appropriate engagement of professionals across different level for a successful execution of clinical studies. It would be highly beneficial for networks and international organisations, such as EULAR, to collaborate in the development of comprehensive guidelines for defining the roles and responsibilities of professionals involved in clinical studies. An adequate training and recognition could provide a strong foundation for these professionals to tackle the often complex regulatory frameworks, ethical implications, and logistical issues.

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Acknowledgements: NIL.

Disclosure of Interests: Ottavio Secchi: None declared, Federica Lumetti: None declared, Martina Orlandi: None declared, Amelia Spinella: None declared, Marco de Pinto: None declared, Gilda Sandri: None declared, Clodoveo Ferri: None declared, Dilia Giuggioli Boehringer-Ingelheim, Johnson & Johnson.

DOI: 10.1136/annrheumdis-2025-eular.C408

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ABS1228-HPR **ADAPTATION OF THE WHO REHABILITATION COMPETENCY FRAMEWORK FOR INTERDISCIPLINARY CLINICAL TEAMS**

Keywords: Education, Work-related issues, Quality of care, Safety

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Background: To be able to deliver truly effective, person-centered, and evidence-based rehabilitation, a precise understanding of the rehabilitation skills and competencies within an organization is required. The Danish White Paper on Rehabilitation underscores this, calling for structured competency development as a cornerstone of improved rehabilitation outcomes. To ensure progress in rehabilitation outcomes, it is essential to empower employees to recognize their strengths, address blind spots, and take ownership of their professional development. Therefore, a detailed mapping of rheumatology rehabilitation competencies and growth opportunities was needed among the interdisciplinary staff at four specialized Danish rheumatology rehabilitation centers. For managers, this is seen as an opportunity to shape teams—unlock their potential, drive development, and ultimately raise the bar for rehabilitation services and build a culture of excellence in rehabilitation from the inside out.

Objectives: The aim of this study was to establish a clear and detailed overview of the necessary rheumatology rehabilitation competencies in the clinical interdisciplinary teams.

Methods: We adapted the World Health Organization's (WHO) Rehabilitation Competency Framework (RCF) (Figure 1) to fit the specific context of three Sano centers and the Danish Hospital for Rheumatic Diseases in Denmark. Following WHO's official guidelines, the managers formed a project team that included a diverse group of healthcare professionals in rheumatology—physiotherapists, occupational therapists, nurses, and nurse assistants—along with managers, union representatives, and health and safety officers. In addition, an advisory group were established with managers and a researcher. This ensured a broad range of perspectives throughout the process. The adaptation unfolded in several phases, including six full-day workshops and five online follow-up meetings in the project group. Participants engaged in in-depth discussions to refine and agree on the content and structure of the adapted framework. Key activities included an initial Danish translation of the RCF performed by the project team. The team further refined the translation through consultations with stakeholders and other clinicians to ensure accuracy and relevance. When needed, the team sought direct clarifications from the WHO. This collaborative process produced a finely tuned competency framework, carefully crafted to address the specific needs of the involved organizations. To ensure precision, clarity and traceability, all decisions on selection, exclusion, and adaptation were thoroughly documented. The statements underwent iterative reviews within the project team, with continuous feedback to refine the wording.

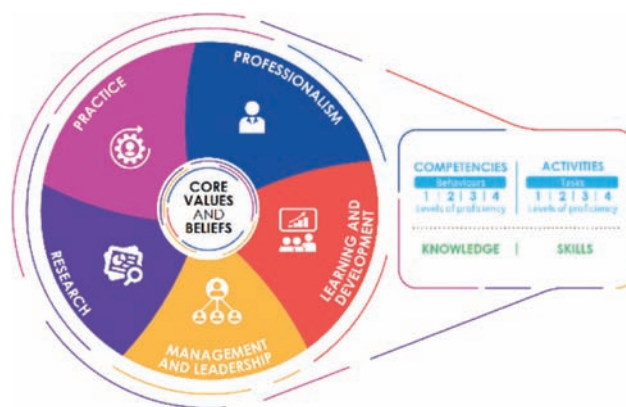


Figure 1. The WHO Rehabilitation Competency Framework¹

Results: The adaptation resulted in 46 carefully crafted statements defining generic rehabilitation competencies across different professional roles. The refined statements were grouped into five domains in accordance with the RCF framework: practice (20), professionalism (11), learning and development (8), management and leadership (5), and research (2).

Table 1. Examples of the chosen expected level of competencies and the original and adapted statements from the practice domain

COMPETENCIES	BEHAVIOURS			
	Level 1	Level 2	Level 3	Level 4
<i>The rehabilitation worker:</i>				
C3. Communicates effectively with the person, their family, and their health-care team	C3.1 Recognizes the communication needs and practices of the person and their family, such as those related to age, education, culture, health condition or language C3.1 I can identify the need to adapt communication and approach to the individual patient based on their age, education, culture, health condition, health literacy, and language skills.			
C3. Communicates effectively and appropriately with the patient and their interdisciplinary team.	C3.2 Adapts communication to frequently encountered needs and practices, including the use of interpreters, assistive technology, and relevant accommodations	C3.2 Adapts communication to a range of needs and practices, including the use of interpreters, assistive technology, and relevant accommodations	C3.2 Spontaneously adapts communication to a range of needs and practices, including the use of interpreters, assistive technology, and relevant accommodations	C3.2 Spontaneously adapts communication to complex needs and practices, including the use of interpreters, assistive technology, and relevant accommodations C3.2 I can independently adapt communication to address complex needs during the patient's course of care, such as the need for an interpreter, technology, and appropriate settings or surroundings.

Key outcomes of the project included:

- Visual tool to map rehabilitation competencies:** The statements from an online questionnaire were incorporated into a visual tool for employee development interviews. This visually engaging and detailed tool maps clinician competencies across the five domains and provides a clear framework to guide development opportunities during annual performance reviews.
- Structured competency assessment approach:** A systematic method was designed to evaluate the staff's ongoing competency development needs, helping to identify training gaps and inform future development initiatives.
- Enhanced insight into individual competencies:** Employees gain a clear understanding of their own skills and need for improvement after mapping their rehabilitation competencies, empowering them to engage more effectively in their professional growth. This process is facilitated through an electronic platform, ensuring easy access and efficient tracking of competencies and development areas.

Conclusion: The adaptation of the WHO Rehabilitation Competency Framework to a specific context resulted in a practical and actionable tool for competency management in clinical practice. By guiding employee development and fostering a culture of continuous learning and self-awareness, this framework has the potential to strengthen professional practice. Ultimately, it is expected to