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Original Clinical Article

JOURNAL OF CHILDREN'S ORTHOPAEDICS

Journal of Children's Orthopaedics
2026, Vol. 20(3) 216–224
© The Author(s) 2026
DOI: 10.1177/18632521261424747
journals.sagepub.com/home/cho

Barriers to conducting prospective multicentre studies in paediatric orthopaedics in Europe: Insights from the EPOS Discoid Meniscus (DiMe) project

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Abstract

Purpose: Prospective multicentre studies represent a cornerstone of evidence-based advancement. However, within orthopaedics, and particularly in the European context of paediatric orthopaedics, such rigorous investigations are notably scarce. This study aims to explore the organizational, regulatory, and resource-related barriers hindering initiation of these crucial studies, using the setup phase of the '*EPOS Discoid Meniscus (DiMe) Project: a Prospective Multicentric Cohort Protocol*'.

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Date received: 25 November 2025; accepted: 26 January 2026

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Methods: A cross-sectional survey was conducted from 19 centres initially recruited for the European Paediatric Orthopaedic Society DiMe Project (NCT05580315) cohort study. Delays and perceived obstacles encountered during initiation phases: contract negotiation, ethics committee approval, and patient enrolment were assessed. A descriptive analysis was performed to characterize the data. Twelve responding centres (63.2%) were still in the contract negotiation phase, while 36.8% ($n = 7$) had progressed to the patient enrolment stage.
Results: Median duration for contract negotiation was 12 months (Q1-Q3: 7–22), matching ethical approval (Q1-Q3: 3–12). Sixty-three point two percent ($n = 12$) of responding centres were still in the contract negotiation phase, while 36.8% ($n = 7$) had progressed to patient enrolment, with 41 patients enrolled across these sites. Formal ethics committee submission was required *de novo* in 84.2% ($n = 16$) of responding centres. Major challenges identified included bureaucratic delays, lack of institutional support, absence of dedicated research staff, and prolonged administrative processes.
Conclusion: The initiation of European multicentre studies in paediatric orthopaedics is hindered by institutional and regulatory barriers. Streamlining administrative and ethical processes and allocation of resources and personnel are needed to improve efficiency and facilitate successful collaborations.
Level of evidence: V – Expert opinion / Cross-sectional survey

Keywords: Europe, prospective study, multicentre study, paediatric orthopaedics, research barriers

Introduction

Prospective multicentre studies stand as a fundamental pillar of evidence-based progress across the entire spectrum of scientific and medical inquiry.[1–4]

By systematically collecting data over time from diverse patient populations across multiple institutions, these studies offer the unique capacity to establish robust causal inferences, identify patterns of disease progression, and evaluate the effectiveness of interventions with a high degree of reliability and generalizability.[5]

This rigour is paramount in orthopaedics,[6] particularly in specialized fields such as paediatric orthopaedics.[7]

Despite this clear and compelling rationale, the landscape of paediatric orthopaedic research in Europe reveals a notable scarcity of large-scale prospective multicentre investigations, suggesting the presence of significant obstacles hindering their conception and implementation.[8] In Europe, researchers face numerous systemic and operational barriers that limit the feasibility and quality of such studies.[9] These challenges are particularly pronounced in paediatric populations, where specific ethical considerations, limited patient volumes at individual centres and logistical complexity create significant hurdles.[7]

Key obstacles include the complexity of Europe's regulatory landscape, with lengthy and fragmented approval processes under Good Clinical Practice guidelines, and the need for multi-centre collaborations to achieve statistically meaningful sample sizes.[10,11] Further difficulties arise from funding and infrastructure limitations, including less financial support compared to adult research, and complexities in recruitment and consent due to language, cultural, and health literacy differences.[12]

Despite these obstacles, early feasibility studies in paediatric surgical contexts have demonstrated that well-coordinated, multi-institutional research is possible, albeit resource-intensive and heavily reliant on clinician engagement and institutional support.[7]

In contrast, the United States has seen the emergence of large, successful multicentre prospective registries in paediatric orthopaedics. Studies such as Justifying Patellar Instability Treatment by Early Results,[13] Pediatric ACL: Understanding Treatment Outcomes,[14] and Research in OsteoChondritis of the Knee[15] provide robust examples of collaborative frameworks that facilitate high-quality prospective research in children.

The European Paediatric Orthopaedic Society (EPOS), recognizing the need for high-quality, prospective data to inform the management of a common yet variably treated condition in children, initiated the 'EPOS Discoid Meniscus (DiMe) Project: *a Prospective Multicentric Cohort Protocol'*. Discoid meniscus, a morphological variant of the knee meniscus, can present with a range of clinical manifestations, from asymptomatic presence to debilitating pain and functional limitations, often necessitating surgical intervention.

Understanding the natural history of symptomatic discoid meniscus, the short-, medium-, and long-term clinical outcomes of these interventions are critical to establishing evidence-based guidelines and lead to future randomised studies. The ambitious, multicentre, international design of the DiMe Project aimed to address these knowledge gaps through prospective data collection.

However, the initial experiences during the launch phase revealed that the anticipated smooth and rapid activation of participating centres did not materialize.

Challenges in the crucial setup phase prompted a formal and systematic evaluation of the specific organizational, regulatory, and resource-related barriers encountered by the participating European centres, with the pragmatic goal of

informing and facilitating future investigator-led prospective multicentre studies in paediatric orthopaedics.

Methods

A cross-sectional survey was conducted to investigate the experiences of European centres during the initiation phase of the 'EPOS Discoid Meniscus (DiMe) Project: *a Prospective Multicentric Cohort Protocol'* (*NCT05580315*).

The DiMe Project is a long-term, prospective, multicentre observational cohort study launched in September 2022 across paediatric orthopaedic and sports medicine centres in Europe. Its primary aim is to describe presentation, management and outcomes of discoid meniscus in children and adolescents. Consecutive patients aged <18 years with symptomatic discoid meniscus confirmed clinically and by MRI are enrolled in the study. The project is non-interventional: diagnostic work-up and treatment decisions (including timing of surgery and surgical technique) remain at the discretion of the treating team, without randomization. Data collected include baseline demographics and clinical presentation; imaging findings; intra-operative details; complications; and longitudinal follow-up data including clinical assessments, patient-reported outcome measures (PROMs), and imaging, with follow-up planned for up to 15 years.

The survey targeted all 19 European centres that had been invited and agreed to participate in the DiMe Project cohort study at the time of the investigation. These centres were affiliated with diverse paediatric orthopaedic institutions or sports medicine units across Europe. No monetary incentives were given to participants. Figure 1 illustrates the flowchart for excluding centres and data.

The anonymous electronic questionnaire was developed by the coordinating centre of the DiMe Project, comprising experienced researchers in paediatric orthopaedics, based on the Checklist for Reporting Results of Internet E-Surveys.[16] The instrument underwent a rigorous internal review process to ensure clarity, logical flow, and comprehensive coverage of the study's objectives. This involved initial drafting by the core research team, followed by iterative revisions based on feedback and collaborative discussions among the investigators. The final questionnaire included 19 questions, structured and semi-structured items, focusing on the timelines and perceived obstacles in 3 different parts: contract negotiation, ethics committee approval, and patient enrolment.

The survey was administered via an online platform. An initial email invitation, containing a unique link to the questionnaire, an explanatory letter detailing the study's aims and the significance of their participation, and a concise overview of the questions, was sent to the designated principal investigators at each of the 19 invited centres. For centres that did not respond within a period of 3 months, a follow-up reminder email was sent to encourage participation. Participants were asked to complete the online questionnaire independently at their convenience, after providing their informed consent electronically by proceeding with the survey. The contact information of the Principal Investigator of this study was provided within the survey materials for any clarifications or queries that may arise during the completion process. Participation was voluntary, and responses were anonymized to encourage honest and open feedback. Completion of the online form was considered as informed consent to participate in the survey.

The estimated time for completing the questionnaire was approximately 10 min. Participants were able to review and revise their responses before final submission, a feature implemented to enhance the accuracy and quality of the collected data.

Data analysis involved the application of descriptive statistics to summarize the reported durations for contract negotiation and ethics approval, the frequency of specific challenges. Categorical variables were summarized using absolute and relative frequencies and displayed through bar plots. Continuous variables were reported as median, first (Q1), and third (Q3) quartiles. Statistical analyses were performed with R software version 4.4.1 (https://www.r-project.org/).

Results

Study participation

At the time of the survey (conducted between August 2024 and February 2025), 2 years after the DiMe Project's initiation in September 2022, responses were received from all the 19 invited centres, yielding a response rate of 100%.

A total of 12 responding centres (63.2%) were still in the contract negotiation phase, while 36.8% ($n=7$) had progressed to the patient enrolment stage (Figure 2).

Contract negotiation

The contract negotiation phase exhibited the most protracted timeline, with a median duration of 12 (Q1-Q3: 7–22) months. The observed range spanned from 2 to 36 months. Commonly reported barriers contributing to these delays included bureaucratic and documentation-related complexities ($n=17$, 89.5%), legislative ($n=11$, 57.9%) and financial hurdles ($n=7$, 36.8%), and a lack of dedicated personnel to provide research support ($n=9$, 47.4%, Figure 3 panel a). Notably, only one centre reported completing the contract negotiation phase within a timeframe of <3 months (Figure 3 panel b). Almost 70% of the centres received support from a research office.

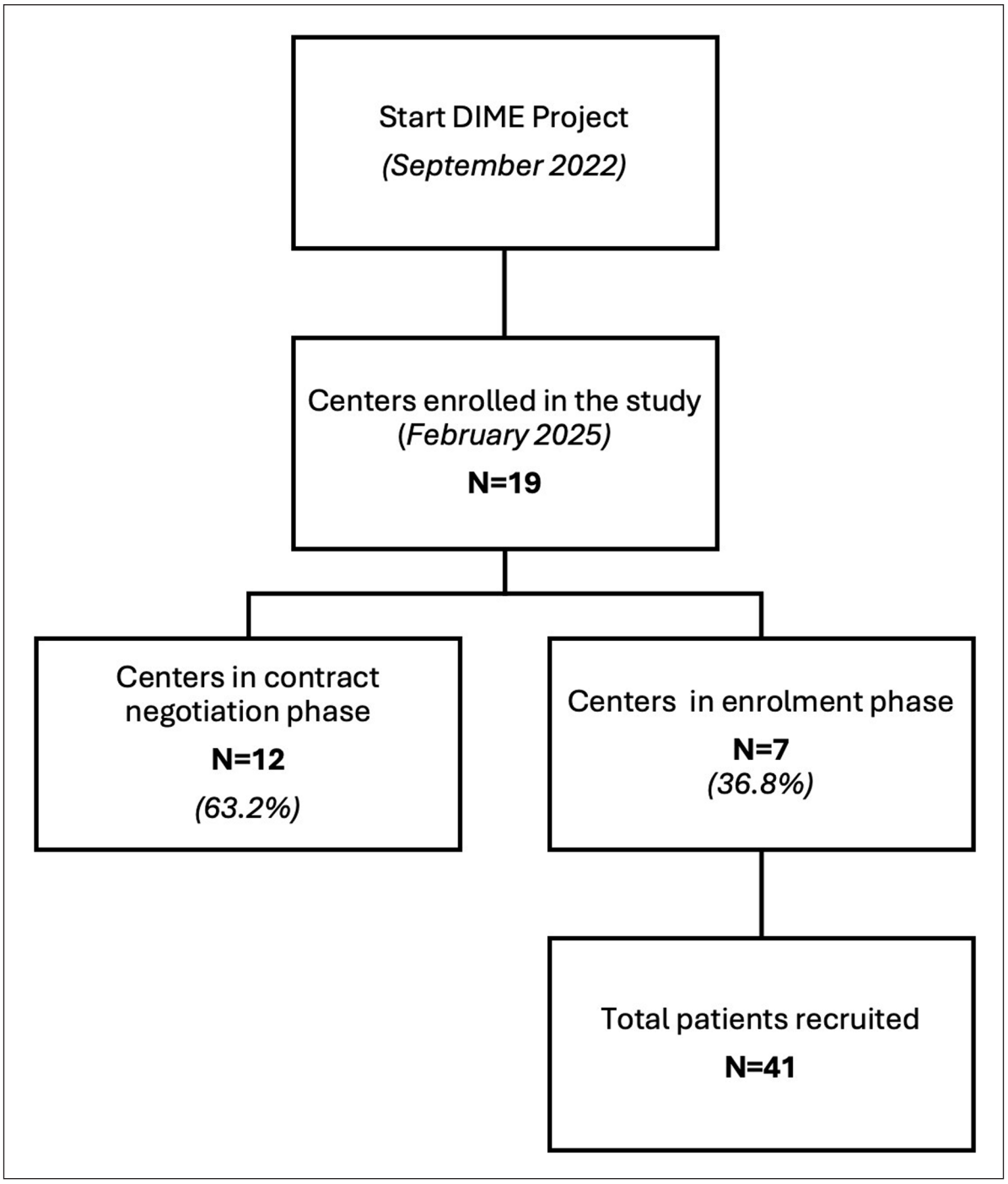

Figure 1. Centres' recruitment process.

Ethics committee approval

In 84.2% of cases ($n=16$), additional ethics committee approval at the participating centre's institution was required, beyond the approval already obtained by the coordinating centre.

Obtaining ethics committee approval also presented a significant bottleneck in study initiation, with a median time of 12 (Q1-Q3: 3–12) months. In 68.2% of centres (13 out of 19), all study documentation (originally provided in English by the coordinating centre) had to be translated into the local language. Financial support for the ethics approval process was required by 22.2% of centres (4 of 18).

At the time of reporting the survey results, 5 out of the 19 responding centres (26.3%) were still awaiting final ethics committee approval. Frequently cited issues contributing to these delays encompassed requests for document rewriting and resubmission and challenges associated with

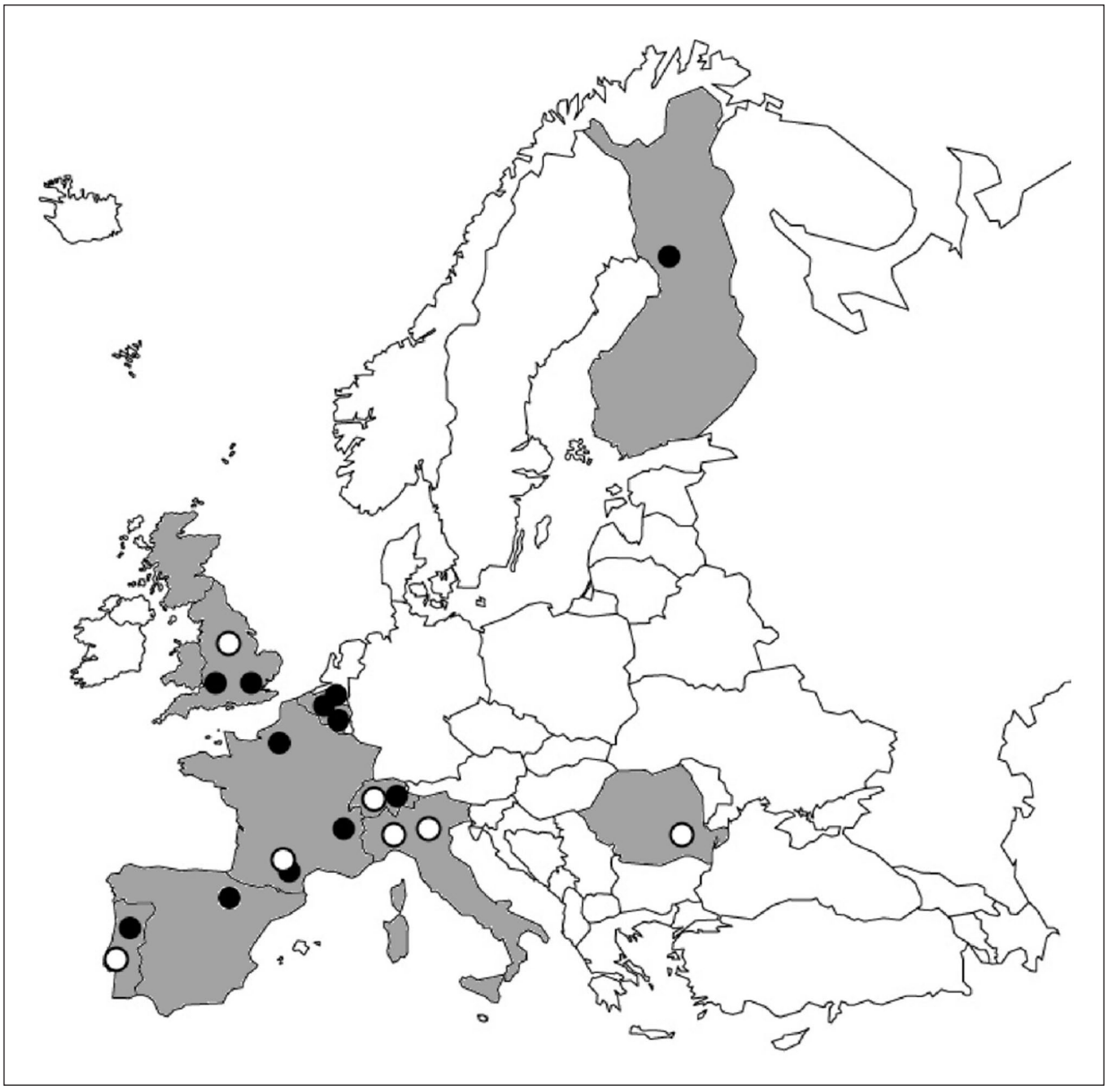

Figure 2. Geographic distribution of 19 participating centres in the EPOS DiMe Project across Europe.
Shaded areas indicate the countries involved in the study. Each circle represents a participating centre: white circles correspond to centres that have initiated patient recruitment, while black circles indicate centres that are still in the contract negotiation or ethics committee approval phase. DiMe: Discoid Meniscus; EPOS: European Paediatric Orthopaedic Society.

language translation of study documentation ($n=6$, 31.6%), with 3 centres (15.8%) reporting issues related to insurance (Figure 4 panel a). Eight centres (42.1%) identified the length of time to obtain local ethics committee approval as the primary problem, 7 (36.8%) highlighted problems with the request of documents, 5 (26.3%) cited financial issues, and 4 reported no problems (Figure 4 panel b).

Patient enrolment

Among the 19 centres that responded to the survey, only 7 (36.8%) reported actively enrolling patients into the DiMe Project at the time of data collection. A total of 41 patients had been recruited across these centres, with the coordinating centre having enrolled 18 patients.

The primary reason cited by 6 centres for delays in commencing patient enrolment included time constraints associated with the uploading process (31.6%), followed by the absence of dedicated staff to support the conduct of non-funded clinical trials ($n=5$, 26.3%), and the great quantity of collected data ($n=4$, 21.1%). Only three centres highlighted recruitment difficulties potentially stemming from the timing of study setup in relation to local resources and priorities (15.8%) (Figure 5 panel a).

Regarding the enrolment phase, 10 out of 19 centres (52.6%) reported a perceived need for dedicated staff and

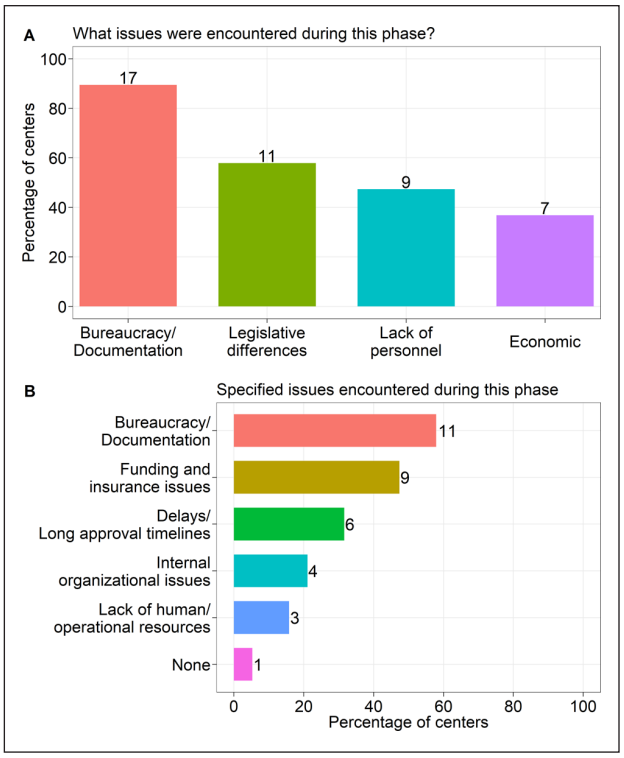

Figure 3. Contract negotiation delays across participating centres. (a) What issues were encountered during this phase? (b) Specified issues encountered during this phase.

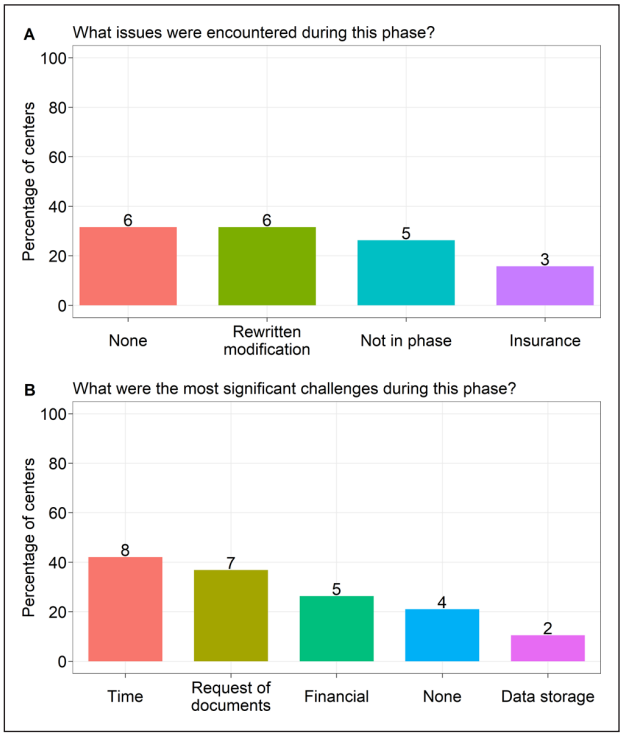

Figure 4. Timeline for ethics committee approval. (a) What issues were encountered during this phase? (b) What were the most significant challenges during this phase?

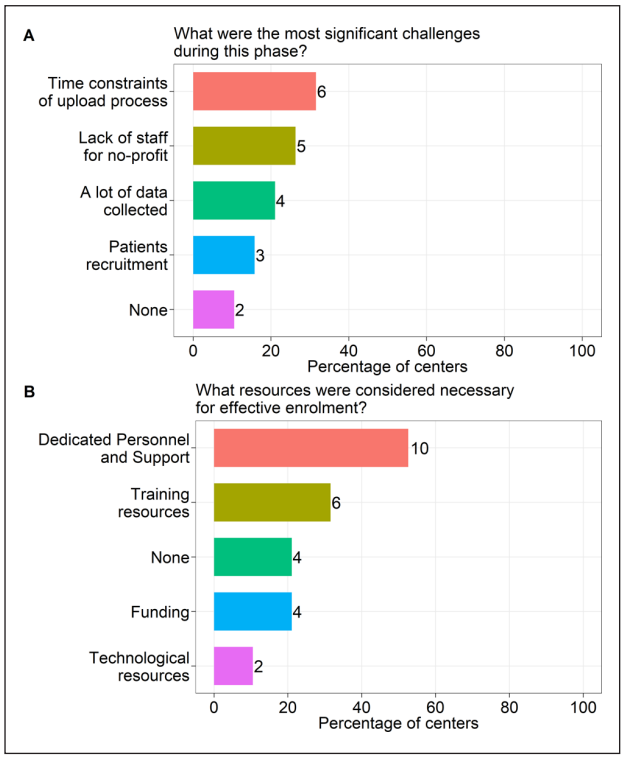

Figure 5. Patient enrolment status (a) What were the most significant challenges during this phase? (b) What resources were considered necessary for effective enrolment?

external support. Six centres (31.6%) highlighted the importance of training resources, and 4 centres cited the necessity of funding (21.1%). Only 2 centres (10.5%) reported a need for technological resources (Figure 5 panel b).

Almost 83% of centres (14 out of 17) reported that they felt they had received help from the coordinating centre.

Perceived resource needs and recommendations for study implementation

When centres were queried regarding essential resources for effective study implementation, several key themes emerged. A shared European ethics committee would streamline approval. Frequent meetings and communication between centres are crucial. Dedicated funding and a research coordinator at each centre are needed for proper data management and patient monitoring. A digital PROM system would improve data collection efficiency. Funding for insurance and ethics approvals, and personal investment from researchers, in terms of time, effort, and dedication, are also necessary.

Discussion

This study highlights the considerable organizational and regulatory difficulties that hinder the initiation of

prospective multicentre studies in paediatric orthopaedics in Europe. Using the EPOS Discoid Meniscus (DiMe) Project as a representative case, we found that even highly motivated centres faced prolonged timelines for contract negotiation and ethics approval – both with a median duration of approximately 1 year. Notably, more than half of the responding institutions were still unable to begin patient enrolment 2 years after the project's initiation. These findings underscore the magnitude of administrative and structural barriers that impede the conduct of high-quality, collaborative research in this field.

Our results provide new empirical evidence to a problem long recognized but rarely quantified in European orthopaedics. Prior studies have discussed the multifactorial challenges of prospective research, including patient recruitment, limited funding, and inadequate infrastructure.[12] A primary hurdle in orthopaedic studies is patient recruitment and retention. Because many orthopaedic conditions require surgery, patients may be reluctant to participate in trials that involve randomization or receiving a non-preferred treatment, leading to insufficient patient accrual and, frequently, trial discontinuation.[17–19] Furthermore, maintaining high follow-up rates is difficult due to the long-term nature of many orthopaedic outcomes, increasing the risk of bias and reduced study power from patients being lost to follow-up.[19] Study design is complicated by the heterogeneity of interventions and patient populations. Standardization is difficult because surgical techniques, surgeon expertise, and patient comorbidities can vary widely, potentially confounding results. While expertise-based trial designs can address differential expertise bias, they add significant logistical complexity.[20] Finally, there are challenges in outcome selection and measurement. While patient-reported outcomes are increasingly utilized, they must be demonstrably valid, reliable, and sensitive to change.[20,21] The prolonged timelines we report are significantly longer than those described in successful North American collaborative networks,[13–15] suggesting that systemic differences – particularly in ethics and contract procedures – may uniquely disadvantage European investigators.

The heterogeneity of ethical and legal frameworks across Europe appears to be a major contributor to these delays. Consistent with prior reports,[22] most centres required a full, *de novo* ethics submission. These submissions often required mandatory translation of study documents and adherence to site-specific administrative procedures. Additionally, many centres reported a lack of institutional research support or dedicated staff, issues that can significantly increase the administrative workload and lead to burnout among clinicians.[23]

Beyond administrative hurdles, our findings have broader implications for the feasibility of clinical research in European paediatric orthopaedics. The time and resources needed to launch even a non-interventional, observational cohort suggest that many potentially valuable projects may never reach the recruitment stage. This translates to a persistent reliance on retrospective data and single-centre studies, which limits the generation of robust, generalizable evidence. Therefore, establishing dedicated infrastructure – such as institutional research coordinators, centralized ethics approval systems, and secured funding for non-profit academic studies – would substantially enhance the efficiency and sustainability of collaborative efforts.

Our results also highlight the potential for coordinated European research networks, under the guidance of organizations like the EPOS, to overcome fragmentation. Regular communication between centres, shared digital platforms for data entry and PROMs, and standardized templates for contracts and ethics submissions could meaningfully reduce the time from study conception to enrolment. The creation of a shared European ethics review system, already advocated in other medical disciplines, could represent a transformative step toward harmonizing and ensuring equity in paediatric orthopaedic research opportunities.

From a pragmatic operational standpoint, early timelines and onboarding quality could be improved by initiating recruitment in centres that have already completed all regulatory and contractual requirements; however, restricting participation to 'ready' sites may inadvertently favour institutions with greater administrative capacity, thereby reducing representativeness. We therefore propose a tiered, phased activation model: a core group of ready centres begins enrolment immediately, while additional centres join in subsequent waves once predefined site-readiness criteria (e.g. ethics/contracting completion and identified data-entry resources) are met.

Several European paediatric research domains – including paediatric oncology, cerebral palsy registries, and large preterm birth outcome cohorts – show that cross-border multicentre studies become feasible when supported by mature network governance, centralized infrastructure, and dedicated funding streams. In these settings, sustained support from public programmes, foundations and patient advocacy organizations (and sometimes industry) enables shared platforms and a dedicated research workforce (trial units, research nurses, data managers) that can absorb much of the regulatory and operational workload. By contrast, investigator-led paediatric orthopaedic studies often start with limited or no dedicated funding, shifting start-up tasks to clinicians and local teams, amplifying delays and potentially concentrating participation in administratively stronger centres; strengthening central coordination, shared digital tools, standardized templates, and a structured start-up package may help reduce this gap and improve equity across European centres.

Several limitations should be acknowledged. First, the survey design inherently relies on self-reported data, which may be subject to recall bias. Second, the study

focuses on the setup phase of a single project (the DiMe cohort), and while the participating centres represent diverse European countries, the findings may not be universally generalizable to all paediatric orthopaedic research initiatives. Finally, the cross-sectional nature of the analysis prevents an assessment of longitudinal improvements that may arise from the recent implementation of the EU Clinical Trials Regulation. Nonetheless, the consistent patterns observed across countries and institutions lend robustness to the conclusions.

In summary, this study demonstrates that initiating prospective multicentre studies in European paediatric orthopaedics is hindered by pervasive administrative, regulatory, and infrastructural barriers. Addressing these challenges will require coordinated efforts among professional societies, ethics authorities, and funding bodies to streamline approval processes, allocate dedicated research personnel, and promote sustainable multicentre collaboration. Such reforms are essential to enable the generation of high-quality, prospective evidence capable of guiding clinical practice and improving outcomes for children with orthopaedic conditions.

Conclusion

The initiation of large prospective multicentre studies in paediatric orthopaedics within Europe is significantly hindered by substantial institutional and regulatory barriers. Streamlining and standardizing administrative and ethical processes, alongside the allocation of dedicated resources and personnel, appear vital for improving research efficiency and facilitating the successful execution of such crucial collaborative efforts.

Author contributions

Marco Turati, Marco Crippa, Nicolas Nicolaou, Marco Bigoni, Franck Accadbled contributed to the study conception and design. Material preparation and data collection and analysis were performed by Marco Turati, Nicolas Nicolaou, Monika Thüsing, Jaakko Sinikumpu, Aurélien Courvoisier, Joao JLGF Cabral, Julio Duart, Benjamin Tschopp, Stéphane Tercier, Gyözö Lehoczky, Simon Vandergugten, Andrei-Vasile Maxim, Nev Davies, Lucrezia Montanari, Marco Bigoni, Franck Accadbled. The first draft was written by Marco Turati, Marco Crippa, Nicolas Nicolaou, Elena Tassistro, Franck Accadbled. Statistical analysis was conducted by Marco Crippa, Elena Tassistro and Stefania Galimberti. Review, editing, and formal analysis were performed by Marco Turati, Nicolas Nicolaou, Monika Thüsing, Jaakko Sinikumpu, Aurélien Courvoisier, Joao JLGF Cabral, Julio Duart, Benjamin Tschopp, Stéphane Tercier, Gyözö Lehoczky, Simon Vandergugten, Andrei-Vasile Maxim, Nev Davies, Lucrezia Montanari, Marco Bigoni, Franck Accadbled. Project administration was conducted by Marco Turati, Nick Nicolaou, Marco Bigoni, Franck Accadbled.

Data availability statement

Data available on request from the authors.*

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Ethical approval

This study was approved by the Ethical Committee of Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy (Approval Code: DIME). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
This article does not contain any studies with animals performed by any of the authors.

Informed consent

The survey was anonymous and did not require informed consent.

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Submission declaration

This manuscript has not been published previously and is not under consideration for publication elsewhere. The publication of this article has been approved by all authors and by the responsible authorities where the work was carried out. We declare that, if accepted, this manuscript will not be published elsewhere, including electronically in the same form, in English or in any other language, without the written consent of the copyright-holder.

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