Research Involvement and Engagement

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Why involvement remains fragile: a qualitative comparison of principal investigators' and patient organisations' perspectives in Italy

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Abstract

Background Patient Public Involvement is increasingly promoted to enhance the relevance, feasibility, and ethical grounding of clinical research, particularly in oncology, where trials can be demanding, and quality-of-life trade-offs are substantial. Despite this, involvement often remains fragile and inconsistently embedded in routine trial practices, especially where shared operational standards are limited. This study examines why involvement remains difficult to institutionalise in Italy, that is, to move from informal, individually dependent practice toward formally recognised and stable roles within research routines, by comparing perspectives from principal investigators and patient organisation representatives.

Methods We conducted 34 semi-structured interviews with principal investigators and patient organisation representatives and analysed the data using inductive thematic analysis. Interviews were audio-recorded with consent, transcribed verbatim, and analysed using an inductive thematic analysis. Through iterative coding and thematic clustering, recurring barriers and areas of convergence and divergence between stakeholder groups were identified. The resulting themes were subsequently organised into four cross-cutting dimensions—cultural, organisational, operational, and institutional—to support comparison and reporting.

Results Participants in both groups described a shared set of interrelated barriers but interpreted and prioritised them differently. Cultural barriers centred on tensions around expertise, authority, and the perceived legitimacy of experiential knowledge in trial design. Organisational barriers included fragmentation within the patient organisation landscape and misalignment of priorities between scientific endpoints and patient-relevant concerns. Operational barriers reflected workload pressure, limited integration of involvement into trial workflows, and asymmetries in language and expertise that constrained informed participation. Institutional barriers included discontinuity, limited feedback to patients and organisations, and the absence of clear guidance on when and how to engage patients consistently. Together, these factors contributed to involvement being late, episodic, and dependent on individual initiative rather than routine practice.

Conclusions Involvement in Italian oncology research remains fragile because multiple barriers intersect across culture, organisation, operations, and institutions, rather than acting in isolation, while stakeholders often hold different assumptions about roles and value. Strengthening involvement requires more explicit operational guidance,

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dedicated resources, and shared capacity-building to support earlier, more consistent, and more sustainable collaboration.

Plain English summary

Patients and patient organisations are increasingly encouraged to contribute to clinical research so that studies better reflect real-life needs and are easier, fairer, and more relevant for those taking part. This is especially important in cancer research, where treatments and clinical trials can be long, complex, and disruptive to everyday life. However, in Italy, patient involvement is still not routine in research and often depends on individual researchers' willingness. In this study, we explored why this happens by interviewing two groups: principal investigators, who design and lead clinical studies, and representatives of patient organisations, who support patients and often interact with research teams. We asked about their experiences and about the main difficulties that make patient involvement hard to achieve in practice. Both groups recognised many of the same problems, but often understood them differently. Some barriers are linked to culture and professional roles, including uncertainty about who should influence research decisions and how much value should be given to patients' lived experience. Others are organisational and practical, such as fragmented collaboration, lack of time, heavy workloads, and limited resources. Communication is another challenge, especially when research is presented in highly technical language that non-specialists find difficult to understand. There are also broader system-level problems, including a lack of continuity, limited feedback to patients and organisations, and no clear shared guidance on how involvement should happen. Overall, patient involvement remains fragile because these barriers interact with one another. Clearer guidance, dedicated support, and shared training could help make involvement earlier, more consistent, and more meaningful.

Keywords Patient organisations, Patient and public involvement, Principal investigators, Clinical trials, Research involvement, Oncology

Introduction

Over the past decade, the involvement of patients and patients' organisations has become increasingly prominent in clinical research [1–3]. Patient and public involvement (PPI) refers to research carried out *with* or *by* patients and the public rather than *to*, *about*, or *for* them, encompassing their contribution to shaping health research design, conduct, governance, and dissemination [1, 4–12]. Patient engagement (PE) in research emphasises the collaborative relationship through which such involvement occurs. Harrington et al., as reported by Faulkner et al., define it as "the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision-making is guided by patients' contributions as partners, recognising their specific experiences, values, and expertise"[5, 13]. While the term "engagement" is also used in parts of the literature, particularly in North American and pharmaceutical-sector sources, to describe patients' contribution to research processes, this study refers to "involvement" consistent with the operational focus of the study on patients' and patient organisations' contribution to research design, conduct, and governance, rather than to their own clinical care.

A growing body of literature reports benefits associated with incorporating patient perspectives into research [4, 14–20]. These include greater recognition and inclusion of patients and the introduction of experiential perspectives that can challenge established assumptions and enrich researchers' decision-making [5, 18, 21–24]. PPI is therefore increasingly understood not only as an ethical commitment, but also as a pragmatic strategy for improving the relevance, quality, and effectiveness of research [21, 25].

The relevance of PPI is particularly evident in oncology, where clinical trials are often long and complex, involve multiple treatment phases, and entail substantial side effects with profound implications for patients' Quality of Life (QoL) [1, 26–31]. Moreover, oncology is characterised by a high volume of clinical trials aimed at evaluating innovative therapies, making it crucial that patients' perspectives are adequately considered when defining research questions, endpoints, and acceptable trade-offs between treatment efficacy and QoL [1, 15, 28, 31, 32]. Compared with other therapeutic areas, oncology has also developed a relatively strong tradition of collaboration between researchers and patient organisations, making it a particularly informative setting for exploring both the potential and the limitations of PPI. Despite its growing endorsement, PPI remains difficult to institutionalise in practice. In this paper, institutionalisation refers to the process by which involvement moves from informal, ad hoc, and individually dependent practice toward formally recognised, stable roles and procedures embedded in research routines. While numerous frameworks, recommendations, and policy initiatives promote greater patient involvement, operational guidance is often limited, and involvement activities risk becoming tokenistic

or poorly embedded within research processes [8, 16, 22–25, 33–35]. Moreover, many existing approaches insufficiently account for the complexity of PPI, which can take different forms across research phases and typically involves a broader constellation of actors beyond clinicians and patients alone [36, 37]. This gap between normative aspirations and everyday practice raises pressing questions about what constrains PPI, and the conditions under which it can be realised in a meaningful, non-tokenistic way.

This paper focuses on Italy, where PPI are increasingly visible in policy agendas and scholarly debate. Within this context, the study investigates barriers to involvement in clinical research that impede the attainment of its anticipated benefits. To develop a more comprehensive account, we draw on two complementary qualitative analyses of stakeholder groups central to oncology clinical trials: principal investigators (PIs), who design and conduct studies, and patient organisations (POs), which represent patients' interests and often mediate between patients and the research community.

PIs and POs occupy distinct yet interdependent positions in the research ecosystem. PIs typically prioritise methodological rigour and clinical effectiveness, with a strong emphasis on scientific and regulatory requirements [38]. POs, by contrast, are closely attuned to patients' lived experience and may provide psychological, logistical, or financial support, while also advocating for patients' needs within institutional arenas [39, 40]. Considering these perspectives together is essential to understanding how involvement can be both evidence-informed and experience-grounded, feasible within operational constraints, and sustainable through clearer roles and capabilities across actors. Accordingly, we compare and integrate PIs' and POs' views to identify convergent and divergent understandings of involvement barriers and to surface organisational, cultural, relational, and systemic challenges. In doing so, the study contributes to ongoing debates on how PPI can move beyond rhetorical commitment toward more structured, durable, and consequential practices in clinical research.

Methods

This study adopted a qualitative research design using inductive thematic analysis [41], drawing on 34 semi-structured interviews [42] to investigate barriers to PPI in oncology clinical research from the perspectives of principal investigators and patient organisations: POs ($n = 13$) and PIs ($n = 21$) (Tables 1 and 2).

POs were identified with the support of the Italian association of patient organisations in support of cancer patients and their families (Federazione delle Associazioni di Volontariato in Oncologia, FAVO), which facilitated access to organisations involved in patient advocacy and research-related activities thanks to its role as an interlocutor with political, cultural and labour institutions [43].

PIs were identified through a combination of contacts provided by FAVO and the research team's professional networks; additional interviewees were subsequently identified through snowball sampling, as several PIs suggested colleagues with relevant experience during the course of the interviews. They were recruited from Italian research institutes active in oncology and related clinical fields. For both groups, purposive sampling aimed to maximise diversity in terms of geographical area, years of experience, and prior exposure to involvement activities (Tables 1 and 2).

Patient organisation representatives participated in this study providing their perspectives on involvement practices in oncology research, through some ad hoc interviews. FAVO contributed to refining the semi-structured interview guide by providing feedback before facilitating access to POs. However, the study aimed to analyse patient and public involvement as an object of inquiry rather than to conduct the research through a

Table 1 Patient organisations interviewees

PO ID	Geographical area	Target pathology
PO1	Southern Italy	Cancer (generic)
PO2	Italy and Europe	Prostate cancer
PO3	Italy	Cancer associated with genetic mutations
PO4	Southern Italy	Cancer (generic)
PO5	Northern Italy	Breast cancer, Onco-haematology
PO6	Northern Italy	Bladder cancer
PO7	Italy	Laryngeal cancer
PO8	Northern Italy	Gynaecological cancer
PO9	Southern Italy	Gynaecological cancer
PO10	Northern Italy	End-stage cancer
PO11	Italy	Cancer (generic)
PO12	Italy	Breast cancer
PO13	Northern Italy	Long-term patients and cancer survivors

Table 2 Principal investigators interviewees

PI ID	Geographical area	Target pathology
PI1	Milan	Lung cancer
PI2	Reggio Emilia	Psyco-oncology
PI3	Rome	Sarcoma and rare cancers
PI4	Rome	Solid cancers
PI5	Verona	Lung and urological cancers
PI6	Verona	Breast and gynaecological cancers
PI7	Milan	Melanoma and solid cancers
PI8	Forlì	Urogenital cancers
PI9	Rome	Parkinson and neurodegenerative diseases
PI10	Rome	Neurology
PI11	Rome	Breast cancer
PI12	Forlì	Hematology and biostatistics
PI13	Forlì	Hepatobiliary and pancreatic cancers
PI14	Forlì	Data scientist
PI15	Milan	Experimental immunology
PI16	Verona	Radiotherapy oncology
PI17	Reggio Emilia	Palliative care
PI18	Milan	Genomics of cancer
PI19	Rome	Neurology
PI20	Forlì	Clinical nursing
PI21	Milan	Breast cancer

co-production approach; consequently, PO representatives were not involved in the data analysis or interpretation of the findings.

All interviews were conducted remotely, audio-recorded with participants' informed consent, and transcribed verbatim. The interview guide explored participants' prior experiences with patient involvement, perceived barriers and facilitators, organisational and procedural conditions, and suggestions for improving involvement practices across different stages of the clinical research process. To reduce the risk of interpretive bias, transcripts were independently double-coded by two pairs of researchers from the study team, one pair working on PI interviews and the other on PO interviews; discrepancies in coding were resolved through discussion until consensus was reached. The interview guides for both groups were jointly developed by the research team to ensure comparability of the dimensions explored across the two stakeholder groups.

Data analysis followed a two-stage qualitative approach based on an inductive thematic approach, whereby recurring concepts identified in the transcripts were progressively grouped into thematic clusters, which were then organised into broader analytical categories through iterative re-coding of the material against these clusters. In the first stage, participants' experiences of patient organisations' involvement were analysed using an existing framework derived from the literature [44]. This initial stage was primarily aimed at systematically describing how PPI had been implemented in practice, based on the interviewees' experience, and at gathering information about the actual context in Italy, regardless of theoretical notions. In the second stage, interview transcripts were analysed to identify barriers to PPI directly from participants' accounts. Instead of applying a predefined framework, the analysis followed the structure of the interviews and proceeded through iterative coding and comparison. Reported difficulties, tensions, and critical situations were progressively grouped into recurring thematic clusters across interviews, leading to the identification of the main categories of barriers presented below.

This inductive process resulted in six clusters of barriers. In a subsequent interpretative step, these were organised into four cross-cutting dimensions - cultural, organisational, operational, and institutional - which provided a coherent lens for structuring and presenting the findings. While additional aspects emerged during the analysis, this article focuses specifically on the barriers, as other elements primarily served to deepen the understanding of the Italian context beyond the scope of the present paper.

Ethical approval was obtained from the ethics committee of Politecnico di Milano. All participants provided informed consent before participation, and all data were anonymised to ensure confidentiality and compliance with applicable privacy regulations.

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federated platform for the collection, sharing, and analysis of scientific and clinical data across 51 Scientific Institute for Research, Hospitalisation and Healthcare (Istituti di Ricovero e Cura a Carattere Scientifico, IRCCS). These institutions combine clinical care with biomedical and health services research, making them key partners in advancing patient involvement in oncology research and care [43].

Results

This section presents the main barriers to involvement identified through the interviews with PIs and PO representatives. While both groups recognised these barriers, they were often interpreted differently, reflecting their distinct roles and perspectives within the research ecosystem. Barriers are organised across four analytical dimensions: cultural, organisational, operational, and institutional.

Cultural resistance and professional identity in negotiating expertise and authority in study design

POs identify a deep cultural tension stemming from researchers' perceptions of their roles. In their opinion, PIs are not adequately prepared to incorporate patients' perspectives, or those of their representatives, into the design and delivery of clinical trials. According to the PO representatives interviewed, researchers are convinced that scientific expertise is the sole legitimate measure for decision-making, especially in the earliest phases of study development. This determines that involvement *"depends very much on the sensitivity of the individual physician. If you find a physician who believes in it, then something can be done [...] otherwise, patient involvement does not happen."* (PO11).

Some POs also report feeling diffidence coming from researchers, as if their presence could harm researchers' authority; to this matter, POs note how they want to be involved not to compete with physicians, whose scientific expertise they recognise as fundamental, but to act as complementors who know patients more closely, and who can help integrate their perspectives to, eventually, better address their needs and concerns. One PO representative clearly states: *"We do not want to replace doctors. [...] The scientific competence of clinicians is unquestionable, [...] what patient organisations bring is the direct experience of the disease."* (PO3).

According to POs, patients experience similar difficulties. The distance and diffidence in researchers' attitude can make patients reluctant to share their views, propose ideas, or openly discuss their experiences and emotions. In some cases, patients appear hesitant to speak freely because they fear that *"saying the wrong thing could somehow affect the relationship with their doctor "* (PO5), with potential consequences for their care journey.

While PIs do not report perceiving patients as hesitant in their relationships, some reflect on the tension in the ecosystem through a different lens: researchers mainly identify themselves as guarantors of methodological rigour, suggesting that other forms of involvement could create confusion around responsibilities and roles. In a few cases, concern is expressed about the possibility of POs making requests that are incompatible with scientific procedures or requirements or trying to influence decisions too much. Involvement is not excluded a priori; however, PIs generally express willingness to involve patients and patient representatives at the level of consultation, on the condition that roles are well defined before collaboration occurs. Few PIs describe a willingness to extend this to partnership, particularly around decisions on study design and scientific procedures. Resistance is mainly linked to uncertainty about boundaries rather than to involvement itself, although the boundary in question is specifically the one between being consulted and having a share in decision-making authority.

Fragmentation and representativeness of patient organisations

Within the already culturally tense context, POs report that they typically operate in a fragmented landscape: numerous organisations exist, each having *"its own history, its own structure, and its own way of working. Sometimes it is not clear who represents whom"* (PO2). According to some representatives, greater coordination among POs would clarify roles and allow more structured collaboration, enabling PIs to identify the right partner more easily.

PIs did not provide substantially different contributions; instead, they aligned with the perception of a highly heterogeneous organisational landscape in which POs operate, identifying fragmentation as a primary driver of uncertainty concerning partner identification and legitimacy.

Fragmentation of priorities in the research ecosystem

The interviews show that POs and PIs identify different needs and preferences, highlighting a fragmentation of priorities embedded in the research ecosystem itself.

POs report that trial design is predominantly driven by clinical endpoints and methodological constraints, leaving patient-relevant dimensions, such as treatment burden, daily functioning, and QoL, only partially translated into concrete study outcomes. One PO representative observes: *"Quality of life is often mentioned but not translated into concrete outcomes. [...] What is scientifically measured in trials does not always reflect what really matters to patients"* (PO8); the remark illustrates how, even when POs are consulted, this consultation rarely translates into partnership over core design

choices such as endpoint selection, confirming a persistent gap between scientifically defined endpoints and what patients experience as meaningful. From the PO's perspective, this reflects a form of formal inclusion without meaningful participation: input is solicited, but rarely alters what is ultimately measured.

From the perspective of PIs, this gap is not primarily the result of indifference to patient input, but of structural limitations linked to the need for scientific validity, standardisation, and comparability across studies. Several patient priorities are described as difficult to operationalise within existing regulatory and methodological frameworks, as clinical research relies on endpoints that are *"clearly defined and measurable"* (PI5), making it harder to incorporate some patient-relevant aspects into trial design.

PPI as a marginal activity under operational overload and limited organisational integration

Both POs and PIs expand on the concept of operational overload due to additional activities required by PPI.

POs' representatives note that PIs already operate in intense conditions and under tight schedules due to clinical practices, administrative and bureaucratic procedures, or regulations. According to POs, such a demanding context results in involvement activities being pursued only when time and resources allow, leaving them outside standard practice and priorities and making them fragmented and less effective. Because involvement is pursued late, it frequently amounts to informing POs of decisions already taken, rather than consulting them whilst choices remain open: *"at that point, the margins for intervention are minimal […] the most important choices have already been made."* (PO6). Early involvement, by contrast, was viewed by POs as the point at which consultation could still translate into partnership over feasibility and study design.

PIs confirm the same interpretation when discussing their own working conditions: heavy workload and increasingly complex regulatory procedures seem incompatible with the additional effort required, and the lack of dedicated funding and support emphasises the limit. Even though many PIs seem aware of the benefits PPI can bring, they appear to see it as an extra to the essential tasks of clinical research, mentioning that *"the priority is to conduct the study correctly and within the expected timelines. […] many activities are considered essential, and patient involvement is not always among them."* (PI18). PIs acknowledge that involvement occurs later as information-sharing after key decisions are made, rather than as consultation while decisions are being discussed. However, they do not consider this a significant issue: in their view, while it might benefit some factors, early involvement risks complicating or delaying trial development. One respondent clearly mentions: *"If you involve external actors too early, there is the risk of slowing down the whole development of the trial. At a certain point, you have to move forward. You cannot keep the protocol open for discussion indefinitely."* (PI16).

Asymmetries in language and expertise limiting informed and active participation

POs identify communication as a key barrier to genuine involvement. Specifically, they report that trials led primarily by researchers are often framed in scientific and technical language, meaning patients *"do not always fully understand what they are being asked to participate in"* (PO8). In such conditions, the lack of comprehension undermines patients' ability to participate actively even where they are formally included, a case of formal inclusion without meaningful participation: presence in a discussion is not sufficient when the language of that discussion itself excludes substantive contribution.

POs representatives read this phenomenon as a direct implication of the already-discussed research culture, which prioritises technical details and precision over patient accessibility and, at times, results in intentional exclusion. Within this context, some respondents from the selected pool of POs argue that they can play a crucial role in mediating language: *"patients need someone who helps them understand what is written. Our task is to explain things in a way that patients can follow."* (PO1). POs suggest they can help turn complex information into understandable elements for patients and assist them throughout the research process.

Conversely, PIs highlight the many complexities of conducting oncology clinical trials, which pose the challenge of balancing clinical accuracy and accessibility, noting that *"some aspects of clinical research are inherently complex; it is not always possible to simplify without losing important information. […] We have to be careful not to oversimplify scientific content."* (PI18).

At the same time, some PIs recognise the challenge and the importance of communicating with non-experts, admitting that training could help solve the problem: patients need to learn some technical terms. In contrast, physicians need guidance on how to communicate appropriately with patients.

Limited continuity and feedback in a fragile involvement ecosystem

From the POs' perspective, involvement appears sporadic and discontinuous, rarely progressing beyond isolated instances of consultation into a stable partnership across projects. Involvement initiatives are often linked to specific projects rather than part of regular practice and are also tied to researchers' personal commitment. Involvement practice then needs to start over every time a new

collaboration begins, which carries the burden of assessing the activities PIs and POs can collaborate on, as well as of getting to know each other's competencies before understanding how to behave with one another; formalised and stable arrangements would overcome such difficulty.

Within this context, POs report a systematic lack of feedback, meaning that even the most basic level of involvement, information, frequently breaks down once data collection is complete. As previously noted, POs are frequently excluded from collaborative processes altogether; however, a more critical issue is that even where some involvement does occur, they are often not informed about whether studies proceed or the reasons for their non-involvement. A specular pattern is observed in patients, though with a distinct nuance. POs report that, even when collaboration does occur and patients are actively and meaningfully involved in the research process, researchers often fail to communicate study results back to them. A key concern raised by POs is that involvement requires patients to make some effort; when patients are not informed about how their contributions have influenced a study's conduct and outcomes, their willingness to participate in future research diminishes, and feelings of mistrust towards researchers are likely to increase.

PIs confirm that the involvement ecosystem is fragile, identifying the lack of shared standards and guidelines as a primary cause. They mention: *"Patient involvement today is not structured, […] there are no clear indications on when and how to involve patients. […] In the end, the risk is that patient involvement remains something occasional."* (PI16). Notably, PIs frame the problem primarily as one of institutional structure rather than of willingness: for involvement to be meaningful, it must first be embedded in clinical practice, with structured guidance on how stakeholders should interact and how certain involvement activities should be carried out, echoing the institutional dimension defined earlier, and reinforcing why individual goodwill alone has proven insufficient to sustain it.

Discussion

The findings highlight that, although PIs and POs are increasingly aware of the value of involvement, its integration into clinical trial practice remains fragile in the sense defined earlier: dependent on individual initiative rather than formally recognised and stable across the research system. Table 3 summarises how the barriers identified in the Results are interpreted differently by the two stakeholder groups. Notably, in nearly every dimension, PIs and POs converge on recognising that a barrier exists, but diverge on what it means and where responsibility for it lies. This seems to be a recurring pattern; Fig. 1 synthetically represents the barrier clusters across four interacting dimensions and how they interplay contributes to a fragile involvement ecosystem.

Rather than acting independently, the four identified dimensions appear to reinforce one another, producing a self-sustaining condition of fragility. Cultural resistance to sharing decision-making authority discourages PIs from dedicating time to involvement activities when in conditions of workload pressure (operational barrier); the result is involvement happening late and inconsistently, reducing the opportunities for Pos to build the coordination needed to be recognised as reliable partners

Table 3 Classification of patient involvement barriers across cultural, organisational, operational, and institutional dimensions

Dimension	Barrier	PO interpretation	PI interpretation	Convergent/divergent
Cultural	Resistance in negotiating expertise and authority	Researchers' unpreparedness to share decision-making; presence perceived as a threat to authority	Safeguarding of methodological rigour and role clarity, not rejection of involvement in principle	Divergent: shared tension, different attribution (illegitimacy of experiential knowledge vs. protection of scientific rigour)
Cultural	Fragmentation of priorities in the research ecosystem	Patient-relevant outcomes (quality of life, burden) marginalised relative to clinical endpoints	Structural necessity of standardisation and regulatory validity, not indifference to patients	Divergent: a value conflict rather than a factual disagreement
Organisational	Fragmentation and representativeness of POs	Heterogeneity undermines POs' ability to be recognised as a unified interlocutor	Same heterogeneity read as a source of uncertainty in identifying legitimate partners	Convergent: one of the few points of shared diagnosis
Operational	Operational overload and limited integration	Involvement is deprioritised and occurs too late to influence key decisions	Time/resource constraints are real; early involvement risks delaying the trial	Divergent: shared recognition of overload, opposite evaluation of its consequences
Operational	Asymmetries in language and expertise	Technical language excludes patients even when formally included	Balancing accuracy and accessibility is a genuine, not merely a willingness, problem	Divergent: shared acknowledgment of the barrier, different views on how solvable it is
Institutional	Limited continuity and feedback	Systemic disregard for patients' contribution undermines trust	Lack of shared standards and guidelines, not individual unwillingness	Divergent: shared diagnosis of discontinuity, different locus of responsibility (individual vs. systemic)

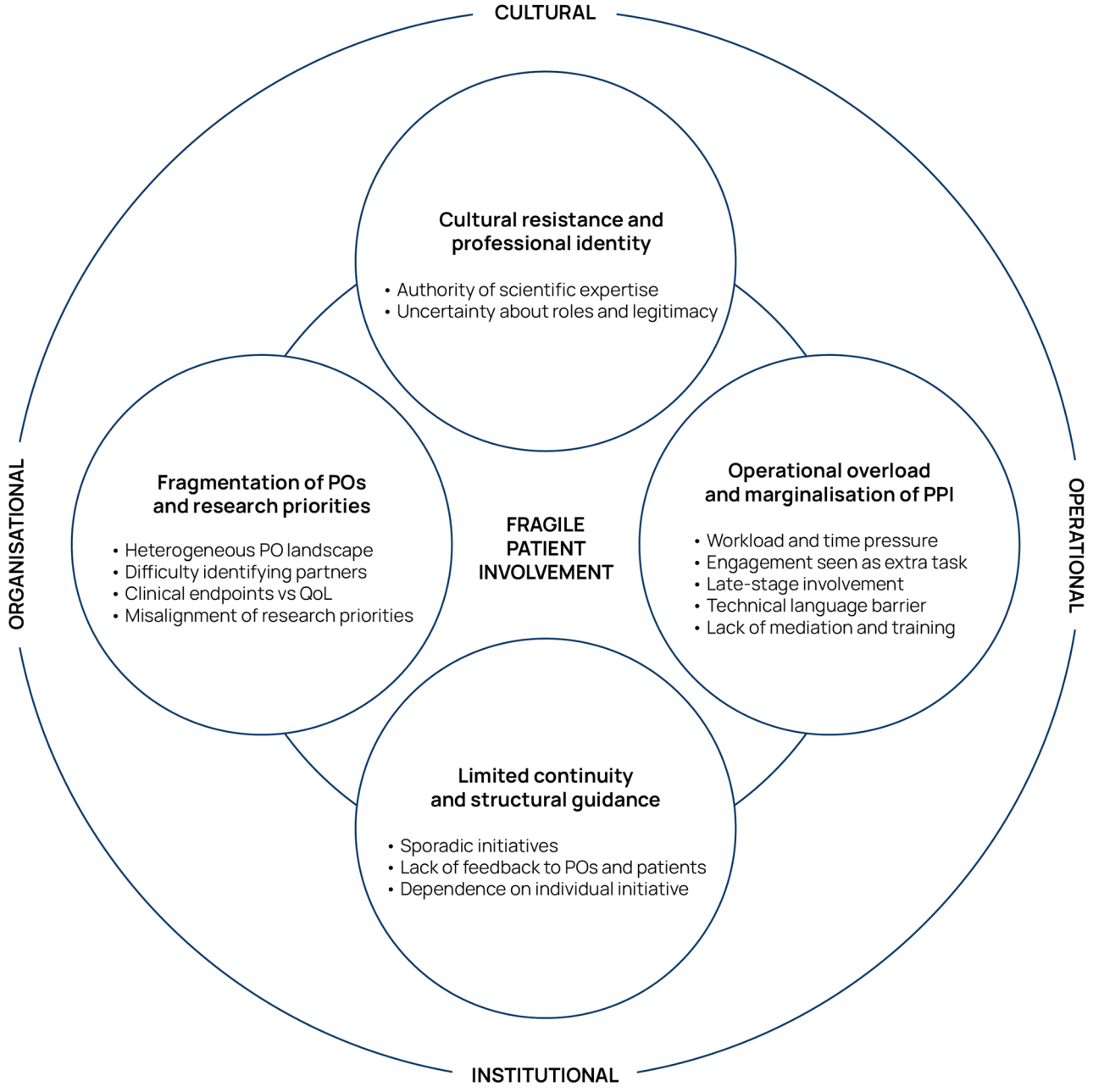

Fig. 1 How different readings of the same system produce fragile patient public involvement

(organisational barrier). Furthermore, the absence of institutional standards specifying when and how involvement should occur leaves every partner unsure of how to interact, and removes any external pressure that could push both parties towards mutual collaboration (institutional barrier). These barriers being in a such interconnected pattern rather than individual, demonstrate how involvement remains dependent on individual initiative, meaning they struggle to become standard practice, while also showing the need of intervening on multiple sides to obtain durable and effective change, rather than acting on one dimension at time. Barriers thus tend to reinforce one an another, creating a mechanism that translates into persistent fragility over the whole system.

Both PIs and POs identify largely overlapping barriers to involvement (Table 3); however, in nearly every dimension, they interpret and attribute responsibility for them differently, depending on their respective backgrounds, experiences, and competencies [35]. This divergence is part of the mechanism sustaining fragility: the misalignment appears as a systemic tension between different logics of value, particularly evident in the asymmetry of objectives that characterises interactions between researchers and POs [15, 32, 45, 46]. PIs may

recognise the relevance of patient-centred concerns, yet they perceive them as secondary when confronted with competing priorities such as scientific validity, regulatory compliance, or time constraints [47], as it emerges from cultural and operational dimensions (Table 3).

Conversely, consistent with existing literature [21, 22, 35, 48], interviews confirm that POs tend to interpret this hierarchy of priorities as a signal that experiential knowledge, although formally acknowledged, is not fully incorporated into decision-making processes, a further example of formal inclusion without a meaningful participation, where presence is granted but not exploited as it does not lead to any influence over outcomes. This does not necessarily reflect explicit disagreement, but rather a somewhat parallel awareness, accompanied by different urgency thresholds. Because neither group's interpretation is explicitly voiced to the other in the absence of structured interaction, this parallel awareness is never tested or revised, allowing divergent assumptions to persist alongside the structural barriers described above, eventually reinforcing it.

Alongside these structural tensions, some barriers are perceived as relatively straightforward and widely acknowledged by both parties. Communication issues, particularly those related to technical language and overly complex materials, are often described as obvious obstacles that could be mitigated through simplification and targeted training, in line with previous studies [45, 46, 49]. From this perspective, improving shared understanding is not seen as conceptually problematic but as a practical challenge requiring dedicated resources, educational efforts, and time investment. Another relevant issue to address is the need for training [50] for the two groups [51, 52]: interview data confirm international evidence, affirming that patients and POs should acquire technical knowledge about scientific terminology and trial processes [5, 47, 53], while researchers could improve their communication and collaborative practice [46, 54, 55]. This reciprocal need points towards a bi-directional model of training in which researchers also develop skills in plain-language communication and collaborative practice, opposed to one-directional model in which experts teach patients how to understand research.

However, building this capacity is not a straightforward undertaking. The EUPATI (European Patients' Academy on Therapeutic Innovation) programme offers a relevant, if partial, precedent: through a structured, multi-year curriculum on medicines research and development, it has trained patient experts across more than twenty countries to participate meaningfully in scientific and regulatory discussions [56]. Its experience suggests that sustained, structured investment is needed to build lasting capacity. At the same time, EUPATI's focus remains primarily on training patients rather than researchers, and operates chiefly in the pharmaceutical and regulatory domain rather than in the design of individual academic or IRCCS-led trials; this underlines that the reciprocal, researcher-facing training called for by respondents in this study remains comparatively underdeveloped internationally.

Beyond individual interactions, respondents emphasised the importance of building relationships between POs and PIs before the formal start of a collaboration. Early and informal connections facilitate mutual understanding and trust, reducing the time typically devoted to role clarification and reciprocal legitimisation [57]. When such relationships are already in place, collaboration during clinical trials becomes smoother, as the preliminary effort required to establish credibility and shared expectations is significantly reduced.

However, the feasibility of early relationship-building is constrained by the fragmentation of the involvement ecosystem [7, 30], which is already visible in the composition of the POs interviewed for this study: regionally-focused organisations outnumbered nationally focused ones (Table 1), limiting the visibility and coordination capacity of any single organisation. Both PIs and POs highlighted the absence of structured mechanisms to facilitate matchmaking, making it difficult for researchers to identify appropriate organisations and for POs to be considered as potential partners. This lack of coordination reinforces ad hoc involvement practices and limits the scalability of successful collaborations.

In some cases, barriers are not merely structural but cultural. The interviews again confirm findings from previous studies [45, 47, 54]: a limited willingness to accept patient involvement persists among certain actors, often rooted in scepticism towards its added value or concerns about the loss of scientific authority. Consistent with the case discussed above, showcasing international best practices to the parties involved could serve as evidence that better results can be achieved when barriers are overcome. Practical, real-world examples, such as the EUPATI experience discussed above, could serve to go beyond theoretical notions, legitimising involvement and eventually reducing resistance.

Importantly, POs consistently stressed that their goal is not to replace clinicians or compete with their expertise, but to work alongside them as complementary actors. Supporting researchers throughout the collaboration process, rather than positioning involvement as an external imposition, is thus a key strategy to implement to foster openness and avoid potential conflicts.

Finally, respondents in some cases mentioned that willingness to involve patients is present, although opposed to a lack of practical knowledge. The literature confirms that uncertainty regarding roles [22, 58], responsibilities [55], and appropriate modes of interaction [54] constitute

barriers to PPI, even when the parties involved are willing to implement them. This gap underscores the need for clear, shared guidelines outlining how involvement should be conducted in practice [16, 23–25, 33, 34]. Such guidance should address not only researchers' behaviours, but also include training for patients and patient organisations, clarifying expectations and supporting all actors in navigating collaboration effectively. This would allow to move, in the terms introduced earlier, from formal inclusion toward meaningful participation, and from consultation toward partnership wherever feasible. At the same time, involvement should become standard practice in clinical research, which can only be feasible if stakeholders formally recognise each other as legitimate partners in research and explicitly set roles and responsibilities for each prior to collaboration, that is, if involvement is institutionalised rather than left to individual discretion.

Conclusions

This study highlights how PPI in oncology trials is shaped not simply by the presence or absence of barriers, but by how principal investigators and patient organisations interpret and attribute responsibility for the same barriers differently (Table 3), and by how these divergent interpretations interact with structural, operational, and institutional constraints to produce a self-reinforcing condition of fragility. Addressing this fragility is therefore unlikely to be achieved through isolated interventions targeting a single dimension; it requires coordinated action across cultural, organisational, operational, and institutional dimensions simultaneously.

The analysis also shows that POs can contribute a complementary perspective, particularly in early trial phases, by surfacing feasibility, communication, and relevance issues that may otherwise remain unaddressed. Advancing involvement, therefore, depends less on individual willingness and more on clearer operational guidance, dedicated resources, shared training, and stable mechanisms for collaboration. In practical terms, this points towards specific, actionable directions: pairing bi-directional communication training (operational) with explicit institutional guidance on when and how involvement should occur across trial phases (institutional); supporting the coordination capacity of patient organisations, particularly where regional fragmentation limits their visibility as potential partners (organisational); establishing structured feedback mechanisms so that POs and patients are informed of how their contribution shaped the research, thereby sustaining trust and future willingness to participate (cultural). Because these dimensions reinforce one another, progress on only one is unlikely to be sufficient without corresponding institutional and organisational support.

Although based in Italy, the patterns observed reflect conditions widely discussed in international literature, and international precedents remain partial and unevenly developed on the researcher-facing side. The findings are therefore applicable beyond this context and offer considerations for integrating patient and public involvement more effectively into clinical trial methodologies across different settings.

Limitations

While diversity in size, geographical area, years of experience, priori exposure to involvement, and focus of the selected interviewees was maximised through purposive sampling, the pool of 34 interviewees is limited and may not represent the entire Italian context. The study is situated within the Italian research context, and regulatory or organisational differences may influence transferability. In addition, perspectives from direct patient participants and the pharmaceutical industries were not included and should be explored in future research.

A further limitation concerns the study positioning with respect to involvement. Patient organisation representatives participated as interviewees providing their perspectives on involvement practices, though they were not involved in the analysis and interpretation of the study itself. This reflects the deliberate design choice to examine involvement as an object of inquiry rather than through a co-productive approach. On the other hand, this implies that the study does not model the partnership-level involvement it discusses. Future research adopting a co-produced design, in which patient organisation representatives contribute to shaping the research questions, analysis, and dissemination, would extend and help validate the interpretations proposed here.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40900-026-00947-9.

Supplementary Material 1

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Author contributions

Federico De Luca conducted interviews, supervised data collection and analysis, prepared the figure, contributed to the development of the theoretical framework and methodology, and revised and edited the manuscript. Andrea Pozzoni and Nicolò Signorelli carried out data collection

and analysis, prepared the tables, and drafted the manuscript. Cristina Masella provided senior supervision, contributed to the overall study design and framing of the manuscript, and secured project funding.

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Data availability
The datasets generated and analysed during the current study are not publicly available due to confidentiality and privacy restrictions. Anonymised data may be shared by the corresponding author upon reasonable request and subject to approval by the Ethics Committee of [hidden].

Declarations

Ethics approval and consent to participate
Ethical approval for this study was obtained from the Ethics Committee of Politecnico di Milano. All participants received detailed information about the study and provided informed consent prior to participation. Interviews were conducted in accordance with applicable ethical standards and privacy regulations.

Consent for publication
Participants provided written consent for the use of anonymised interview excerpts for research and publication purposes.

Competing interests
The authors declare no competing interests.

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