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Patient Autonomy in Oncology Clinical Trial Recruitment: Physician Influence, Trust and Ethical Responsibility. short title : Safeguarding Patient Autonomy: A Physician's Responsibility

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Research Article

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Abstract

Background

Informed consent is a fundamental ethical requirement in clinical research, intended to safeguard participants' autonomy. However, decisions to participate in oncology clinical trials are made in contexts characterised by vulnerability, therapeutic uncertainty and asymmetrical physician–patient relationships. This study aimed to explore how decisions to participate in oncology clinical trials are shaped by interactions between patients and physicians, with particular attention to physician influence, patient autonomy and ethical responsibility.

Methods

An exploratory qualitative study was conducted at a comprehensive cancer centre in France. Semi-structured interviews were carried out with 28 patients who had recently consented to participate in a clinical trial, and interviews were conducted with 18 physicians involved in oncology clinical research. Interview transcripts underwent multidisciplinary thematic content analysis, complemented by lexicometric analysis using IRaMuTeQ, including descending hierarchical classification and correspondence analysis.

Results

Physicians played a central role in shaping access to clinical trials through their selection of protocols, identification of eligible patients and presentation of therapeutic options. Although they acknowledged their influence on patients' decisions, they rarely explicitly addressed the ethical responsibility associated with this influence. Patients' decisions were shaped by multiple interacting factors, including hope for therapeutic benefit, lack of alternative treatments, family expectations and the desire to contribute to scientific progress. Trust in physicians emerged as a major determinant of participation, often outweighing detailed engagement with written information. Nevertheless, trust did not necessarily imply passivity, as some patients actively sought additional information or deliberately delegated decision-making to their physicians.

Conclusions

Consent to oncology clinical trial participation is a relational and dynamic process rather than an exclusively individual decision. Physician influence is not inherently incompatible with patient autonomy, but it entails substantial ethical responsibility. Beyond obtaining formal consent, physicians should foster conditions that enable patients to make decisions consistent with their values, preferences and

priorities. These findings support a relational approach to informed consent that acknowledges vulnerability, trust and the shared construction of decisions.

1. Background

Clinical trials are a cornerstone of contemporary medicine, particularly in the management of diseases that account for a substantial proportion of global mortality, such as cardiovascular diseases, cancer and, in certain regions of the world, infectious diseases [1]. Advances in digital health technologies and the increasing availability of large-scale health data have accelerated scientific discoveries and facilitated the identification of new therapeutic compounds by academic researchers and pharmaceutical companies, generating a growing need for clinical evaluation [2]. Clinical trials therefore represent a source of hope [3], both as a means of generating scientific knowledge and as a driver of medical innovation, within a broader narrative of scientific progress. However, since the Nuremberg trials and the subsequent incorporation of research ethics principles into national legislation (including the Huriet-Sérusclat and Jardé laws in France), their conduct has been subject to a fundamental ethical requirement: the free and informed consent of healthy volunteers or patients participating in research [4, 5]. This requirement is intended to safeguard patient autonomy, one of the four fundamental principles of biomedical ethics, alongside beneficence, non-maleficence and justice [6]. Respect for patient autonomy is therefore not only a fundamental ethical principle but also a core moral value of contemporary medical practice [5, 7].

To protect individual autonomy, legislators have established strict requirements governing the informed consent process for participation in clinical trials, including the provision of written information and sufficient time for reflection before a decision is made. Research ethics committees, particularly the *Comités de Protection des Personnes* (CPPs) in France, are responsible for assessing the ethical and regulatory compliance of research protocols, including the quality of participant information documents and consent procedures. These safeguards are intended to ensure that participants are adequately informed and free to make their own decisions [8]. Nevertheless, the literature consistently highlights the limitations of written information documents, which are often only partially read and understood, or sometimes not read at all [9]. Consequently, signing an informed consent form does not, in itself, demonstrate that the decision to participate was autonomous, voluntary and adequately informed [10].

Patient autonomy must therefore be understood as a context-dependent rather than an absolute concept. Respecting autonomy becomes particularly challenging when patients experience physical, psychological, relational, social, economic or spiritual vulnerabilities. Such vulnerabilities may influence both their willingness to participate in clinical research and the extent to which their consent reflects a genuinely autonomous decision [11]. The process of obtaining consent thus involves multiple tensions. On the one hand, clinical research is driven by a commitment to scientific progress, supported by collaborations between academic institutions, pharmaceutical companies and clinical teams [12]. On the other hand, patients may perceive participation in a clinical trial as an opportunity, offering hope of recovery when standard treatments have failed, or conversely as a constrained choice in the absence of

therapeutic alternatives. This ambivalence places the physician–patient relationship at the centre of the decision-making process. Trust in the physician [13], together with the information provided, may strongly influence patients' decisions to enrol in or withdraw from clinical research [14].

Public perceptions of clinical research, particularly since the COVID-19 pandemic, have sometimes included negative representations of participant recruitment. The use of pejorative expressions such as "guinea pigs" or "experimental subjects" reflects a degree of public mistrust towards clinical research and may undermine trust between the medical profession and society [15, 16]. Against this background, we sought to gain a better understanding of the circumstances in which patients agree to participate in clinical research. Specifically, in the field of oncology, we aimed to explore how decisions to participate in clinical trials emerge through interactions between patients and the physicians proposing enrolment.

Our objective was to examine the extent to which recruitment practices in oncology clinical trials may challenge the effective exercise of patients' decisional autonomy. In particular, we sought to investigate whether, in certain circumstances, patients' agreement to participate might reflect the influence exerted by physicians, consciously or unconsciously, rather than a fully autonomous, voluntary and informed decision. Such situations could suggest the persistence of medical paternalism and raise ethical concerns regarding respect for patient autonomy and the principle of beneficence within the therapeutic relationship [17].

Conversely, we also sought to determine whether the physician's influential role in the decision-making process could be understood within a shared decision-making framework grounded in mutual trust. From this perspective, the proposal to participate in a clinical trial would not be based solely on disease characteristics and available therapeutic options but would also take into account the patient's broader circumstances, including quality of life, family and social environment, living conditions, preferences, expectations and personal values. The physician could therefore recommend the option considered most appropriate to the patient's individual situation while acknowledging and respecting the patient's ultimate decision.

In this context, consent to clinical trial participation may be understood not as a single event formalised by signing a consent form, but rather as the outcome of a decision-making process developed within a trusting physician–patient relationship. Participation in research would thus form part of a collaboratively developed care plan involving the patient, the physician and, when desired by the patient, a family member or informal caregiver.

Our analysis highlights the complexity of this decision-making process. It suggests that consent cannot be reduced to an individual, purely rational choice but instead emerges from the interplay of medical, scientific, social and relational factors. We therefore structure our analysis around two main themes: (1) physician-driven selection processes influencing patients' participation in clinical trials; and (2) the development of the decision to participate as a process shaped by multiple interacting influences.

2. Materials and methods

This research was based on an exploratory qualitative study using interviews with patients enrolled in oncology clinical trials and physicians involved in clinical research.

The study was proposed to 34 consecutive patients newly enrolled in a clinical trial over a two-month period. Patients were initially contacted by a clinical research nurse by telephone when scheduling their first screening visit. Those who verbally agreed to participate were subsequently approached by a member of the research team during their screening visit. The study objectives, which were independent of the clinical trial itself, were explained to participants. Specifically, the study aimed to explore the role of physicians and written information in patients' decisions to participate in clinical trials and their perceptions of the information they had received. Participants were provided with a written information sheet. Interviews were conducted during the screening visit, at a time convenient for each participant, between scheduled medical appointments, thereby avoiding additional visits or unnecessary prolongation of their time at the healthcare facility.

No confidential contact information was extracted from medical records or used specifically to contact patients for this study.

Physicians were contacted by email and invited to participate. Interviews were conducted at their workplace and lasted between 15 and 40 minutes. Participation was voluntary, and physicians were informed that they could withdraw from the interview at any time.

Interview guides were specifically developed for this study. The physician interview guide covered professional roles and responsibilities, criteria for selecting clinical trials and eligible patients, motivations for enrolling patients, knowledge and use of participant information sheets and consent forms, practices relating to patient information, and perceived barriers to trial participation. Given physicians' time constraints, these interviews followed a more structured format, using relatively focused and specific questions.

The patient interview guide explored sociodemographic characteristics, information received about the clinical trial, receipt, reading and understanding of the participant information sheet, motivations for and barriers to participation, and the circumstances surrounding decision-making. These semi-structured interviews enabled us to examine how consent was obtained in practice, including the information provided to participants, their engagement with and understanding of written information, and their motivations for participating in clinical research. The study protocol received a favourable opinion from the Research Ethics Committee of the Federal University of Toulouse on 23 February 2023 (approval number 2023 – 628). Participant recruitment was conducted in accordance with the Declaration of Helsinki. Patients received written information about the study, followed by an oral explanation of its objectives and procedures. All participants provided written informed consent. No health-related data were collected.

2.1. Study population: Sample characteristics

The first dataset comprised interviews with 18 physicians (Table 1). The sample included physicians of different genders (10 men and 8 women), ages (33–67 years), and levels of experience in clinical trials (2–40 years). Most were involved in phase III trials (n = 16), while a substantial proportion also participated in early-phase trials (n = 12).

Table 1
Demographic and professional characteristics of the physicians interviewed (n = 18)

Participant ID	Age (years)	Medical specialty	Clinical experience (years)	Gender
P01	58	Breast oncology	15	Male
P02	67	Nuclear medicine	20	Male
P03	36	Medical oncology	7	Female
P04	48	Medical oncology	17	Male
P05	53	Dermatologic oncology	25	Male
P06	39	Medical oncology	2	Female
P07	39	Dermatologic oncology	4	Female
P08	—	Medical oncology	25	Male
P09	41	Hematology	19	Male
P10	33	Breast oncology / Urology	2.5	Male
P11	33	Medical oncology	10	Male
P12	45	Dermatologic oncology	15	Female
P13	33	Oncology	2	Male
P14	37	Gynecologic and head and neck oncology	7	Female
P15	39	Medical oncology	3	—
P16	55	Medical oncology	20	Female
P17	65	Medical oncology	40	Female
P18	52	Medical oncology	24	Female

Note: Missing data are indicated by an em dash (—).

All physicians worked in oncology-related specialties, including medical oncology (n = 10), breast, urological and gynaecological oncology (n = 3), dermato-oncology (n = 3), haematology (n = 1), and nuclear medicine (n = 1). The number of patients enrolled in clinical trials ranged from 10 to 150 per

physician per year. Physicians with the highest recruitment rates (120–150 patients annually) worked in medical oncology and had between 17 and 25 years of professional experience.

The second dataset comprised interviews with 28 patients (Table 2). Women were more frequently represented than men (16 women and 11 men), potentially reflecting the availability of several phase II and III clinical trials in breast and gynaecological oncology during the recruitment period.

Table 2
Sociodemographic characteristics of study participants (n = 28)

Participant ID	Gender	Age (years)	Reported education	ISCED 2011 level	Occupation
A	Female	60	DEUG in law	5	Accounting secretary
B	Male	63	CAP in painting	3*	Not reported
C	Female	50	Bac + 8, notarial studies	8	Legal professional; notary
D	Male	30–65	CAP in butchery	3	Workshop manager, ready-meal factory
E	Male	57	CAP–BEP in mechanics/milling	3	Metallurgy; agricultural mechanic; quality control; security
F	Female	37	PhD in oceanography	8	Not reported
G	Male	58	BEP–CAP; later law studies	3†	Land development manager
H	Female	65–70	Baccalauréat	3	Accounting, notary office
I	Male	30–65	Bac + 5	7‡	Manager
J	Male	70	Baccalauréat + BTS in hospitality	5	Retired
K	Female	30–65	Baccalauréat	3	Childcare assistant
L	Female	30–65	Bac + 5	7‡	Bar manager
M	Female	68	Bac + 2	5‡	Municipal secretary
N	Female	67	Bac + 6	6	Pharmacist
O	Female	30–65	Bac + 5	5	Primary school teacher
P	Female	74	Primary school leaving certificate	1§	School and cafeteria maintenance worker
Q	Female	67–70	Not reported	Unknown	Not reported

Notes. ISCED = International Standard Classification of Education (2011); CAP = Certificat d'aptitude professionnelle; BEP = Brevet d'études professionnelles; BTS = Brevet de technicien supérieur; DEUG = Diplôme d'études universitaires générales. "Unknown" means that no educational qualification was recorded; "Not reported" indicates missing source data.

ISCED coding follows the UNESCO ISCED 2011 framework and the French national mapping (INSEE). Age ranges and missing values have been preserved from the source table.

Participant ID	Gender	Age (years)	Reported education	ISCED 2011 level	Occupation
R	Female	50	CAP	3	Unemployed; assists husband
S	Female	59	BEP in commerce	3	Unemployed
T	Male	Not reported	CAP	3	Electronics mechanic
U	Female	> 65	Two CAPs; foster-care training	3	Retired; former foster carer and nursing assistant
V	Male	37	Primary School	1	Taxi and ambulance driver
W	Male	32	Bac + 5	7	Quality and food safety engineer
X	Male	59	Not reported	Unknown	Not reported
Y	Female	62	Bc + 3	3	Teacher
Z	Male	66	CAP in mechanics	3	Not reported
AA	Female	62	Bac + 6	6	Pharmacist
AB	Female	71	Bac + 3	6‡	Sales representative; notary clerk; real estate

Notes. ISCED = International Standard Classification of Education (2011); CAP = Certificat d'aptitude professionnelle; BEP = Brevet d'études professionnelles; BTS = Brevet de technicien supérieur; DEUG = Diplôme d'études universitaires générales. "Unknown" means that no educational qualification was recorded; "Not reported" indicates missing source data.

ISCED coding follows the UNESCO ISCED 2011 framework and the French national mapping (INSEE). Age ranges and missing values have been preserved from the source table.

Nevertheless, the sample included patients with diverse ages (30–71 years), educational backgrounds (ranging from completion of secondary education to eight years of higher education), and professional occupations, including law, education, metallurgy, childcare, medicine and electronic engineering.

Regarding how patients first became aware of the possibility of participating in a clinical trial, almost all had been referred by a physician, with only one patient having proactively sought trial participation. Only one patient declined participation after reading the participant information sheet.

2.2. Data collection and analysis

All interviews were audio-recorded, transcribed verbatim and anonymised.

First, we conducted a qualitative thematic content analysis [18], performed manually without the use of specialised qualitative analysis software. The analysis was undertaken by a multidisciplinary team comprising a sociologist, a bioethicist, physicians and a palliative care specialist.

We examined the processes through which clinical trial participation was proposed and accepted, focusing on trial selection practices, motivations for participation, ethical attitudes towards clinical research and science, perceptions of the potential benefits of clinical trials, and tensions between therapeutic innovation, scientific methodology and patient protection.

Lexicometric analysis

To complement the qualitative thematic analysis, a lexicometric analysis was conducted using IRaMuTeQ (Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires), an open-source software package based on the R statistical environment. Physician and patient interviews were analysed separately.

Following corpus preparation and standardisation, a descending hierarchical classification (DHC), based on the Reinert method, was performed to identify distinct lexical classes within each corpus. This method groups text segments according to similarities in their vocabulary and distinguishes classes characterised by specific patterns of word co-occurrence. The resulting classes were characterised by their most representative lexical forms and interpreted in relation to the content of the interviews (supplemental data : lexicometric analysis).

Correspondence analysis (CA) was subsequently used to explore the relationships between the lexical classes identified by DHC. This multivariate statistical method provides a graphical representation of the associations and differences between classes along factorial axes, allowing the identification of lexical proximities and oppositions within the corpus.

Associations between lexical classes and participant characteristics were also explored when relevant. The association between lexical forms and classes was assessed using chi-square statistics, as implemented in IRaMuTeQ.

The lexicometric findings were interpreted alongside the qualitative thematic analysis to provide a more comprehensive understanding of the different dimensions of clinical trial participation and decision-making. This complementary approach enabled us to examine both the content of participants' accounts and the lexical structures underlying their discourse[19].

3. Results

3.1. Physician-driven selection processes influencing patients' participation in clinical trials

Physicians' involvement in clinical trials is not a neutral process. Their engagement involves balancing different types of benefits: scientific benefits related to innovation and knowledge generation; clinical benefits concerning patients' interests; and professional benefits associated with career advancement and recognition, although this third dimension was relatively marginal among the 18 physicians interviewed. These dimensions are closely intertwined and may sometimes conflict. Physicians therefore act as gatekeepers, influencing not only patients' access to clinical trials but also the information they receive about them. Although physicians acknowledge their substantial influence on patients' decisions to participate, the question of their responsibility in this process remains insufficiently explored.

3.1.1. Selection of clinical trials: Between research ethics requirements and the ethics of care

All interviewed physicians described clinical trials as an integral component of cancer care within their professional environment. They worked in a highly recognised comprehensive cancer centre combining clinical care, research and education. The institutional reputation and recognised expertise of its professionals facilitated access to clinical trials, as sponsors frequently approached the centre directly with new research protocols.

"There are different things, different approaches, but we are fortunate to work in a centre where we do a lot of research, and we do it well. As a result, most clinical trials come to us because we are approached directly." (Physician 4, male, medical oncology, 17 years of experience)

Several physicians described having a continuously available "portfolio" of clinical trials covering different stages of cancer treatment, including neoadjuvant and adjuvant therapies, metastatic disease, relapse, and situations in which no therapeutic alternatives remained.

"We have a portfolio of clinical trials, but some of them are trials we actively sought out. Two of us are jointly responsible for developing this activity within the unit. So yes, we have a pool of clinical trials that we know well, because some are proposed directly by sponsors, while others are trials we have actively looked for. Then there is the question of how we offer them to patients..." (Physician 12, female, dermato-oncology, 15 years of experience)

Physicians emphasised both the large number of available trials and the organisational support provided by dedicated research teams, including clinical research associates, early-phase clinical trial units and specialised multidisciplinary tumour boards. Clinical trials were therefore presented not as a peripheral activity but as an extension of specialised cancer care and therapeutic innovation.

"Therapeutic trials are a major priority for us. We cultivate the field, so to speak, and try to open as many trials as possible." (Physician 5, male, dermato-oncology, 25 years of experience)

In this context, the main challenge for physicians was not access to clinical trials but their selection. Physicians identified several expected benefits: scientific benefits (innovation, new treatments and advances in research), clinical benefits (relevance to patient management, additional therapeutic options and potential improvements in patient outcomes), and professional benefits (career development, workload considerations and professional interest). Selecting a clinical trial therefore involved balancing these three dimensions to achieve an acceptable compromise.

First, all physicians reported selecting trials according to their scientific and clinical relevance. Their justifications drew upon principles of medical and research ethics [20]. Several explicitly stated that they only participated in trials in which they personally believed.

"I have refused protocols because I did not agree with them. Intellectually, I would not have enrolled someone close to me in such a trial." (Physician 17, female, medical oncology, 40 years of experience)

"If we have opened a trial here, it is because we believe in it. [...] It represents a considerable commitment, and we need to believe in it." (Physician 3, female, medical oncology, 7 years of experience)

Criteria for selecting protocols included the biological plausibility of the mechanism of action, consistency with clinical needs, innovative potential, likelihood of providing meaningful patient benefit, and relevance compared with existing standards of care.

"We select trials that seem relevant for gynaecological cancers, based on current scientific knowledge, results from preliminary phases, and so on. Then, from this range of trials, we choose those we want to open at our centre." (Physician 16, female, medical oncology, 20 years of experience)

Some physicians also reported declining trials that were excessively complex, duplicated existing therapeutic options, or targeted populations considered too restricted for feasible recruitment.

A second set of selection criteria directly concerned patients' interests. The ethical principle of *primum non nocere*, or non-maleficence, was invoked to justify decisions based on patients' clinical interests or, at a minimum, the avoidance of foreseeable deterioration in their condition. When physicians considered the benefit–risk balance unfavourable, they chose not to enrol patients, revealing tensions between the scientific objectives of research and the ethical obligations of clinical care.

"Absolutely [I believe there is a benefit for the patient], one hundred percent. Otherwise, I would not do it. There is no question of conducting a trial just for the sake of conducting a trial." (Physician 2, male, nuclear medicine, 20 years of experience)

"There is always a genuine ethical tension between the need to generate evidence for the future, which is a fundamental requirement of clinical research, and the need to protect the individual from a potential loss of therapeutic opportunity. But every word matters here: 'potential' loss of opportunity." (Physician 8, male, medical oncology, 25 years of experience)

Physicians thus moved from selecting trials on the basis of their intrinsic scientific and clinical merits to selecting patients whom they considered suitable for particular protocols. This assessment incorporated factors related to patients' quality of life and the potential burden of trial participation. Criteria included patients' living circumstances, geographical distance from the cancer centre, frequency of study visits in relation to their general condition, and their perceived ability to understand the protocol.

"When I think that a patient should not participate in a trial because their condition is too poor or because the trial is toxic, I do not tend to push them. Quite the opposite, I say no." (Physician 15, medical oncology, 3 years of experience)

"For example, patients with cognitive impairment, when you can clearly see that they will sign but will not understand what they are signing, I personally do not offer them participation in a clinical trial." (Physician 7, female, dermato-oncology, 4 years of experience)

Early-phase trials (phases I and II) occupied a particular place in physicians' accounts. Although such trials may be proposed to patients with several remaining therapeutic options, physicians frequently associated them with advanced relapse and the absence of established treatment alternatives. In this context, they emphasised therapeutic uncertainty, potentially severe toxicities, and the fact that clinical benefits may be limited to a minority of participants.

"To be honest, I do not necessarily enrol patients because I find the trial itself interesting. I enrol them because... perhaps this sounds inappropriate, but I enrol them because my patient is in good general condition and because I think the trial might offer some added benefit in their particular case. I do not think, 'Oh, this trial is interesting'; I think, 'This trial might offer something additional.' And I believe everyone thinks this way. It is not simply because I think the trial is well designed. For example, there was a phase III bladder cancer trial that offered a genuine additional benefit to patients. With early-phase trials, however, the decision depends on the mutations identified in the patient's tumour and whether therapeutic alternatives are lacking. Those are essentially the two situations that guide my decision to enrol a patient." (Physician 13, male, medical oncology, 2 years of experience)

Phase III trials were presented as essential for generating robust scientific evidence through comparisons with standard treatments and the statistical demonstration of therapeutic benefit. Physicians generally perceived these trials as involving less uncertainty and risk than early-phase studies. This perception had two consequences: it reduced the ethical tensions associated with proposing trial participation and made physicians more inclined to offer these protocols. Some also considered phase III trials better suited to their professional expertise and clinical practice.

"Personally, I am less comfortable explaining the molecules involved in early-phase trials. I feel less at ease with early-phase studies, both in terms of explaining them and following patients. I definitely prefer later-phase trials." (Physician 14, female, gynaecological and head and neck oncology, 7 years of experience)

3.1.2. Informing patients: Between a commitment to transparency and selective disclosure

Physicians' accounts revealed a strong commitment to transparency. They frequently emphasised the importance of providing clear information and honestly presenting the expected benefits and potential risks of clinical trials.

Nevertheless, the vast majority (16 of 18 physicians) acknowledged that they did not read the participant information sheets for the trials in which they enrolled patients, or read them only superficially or incompletely. Having themselves engaged with only part of the written information, physicians subsequently selected which elements they considered necessary to explain to patients when providing the information sheet.

As demonstrated by Fainzang [14], communication between physicians and patients, although increasingly diverse, continues to reflect elements of medical paternalism. Despite the growing emphasis on patient autonomy, physicians may still withhold certain information, often because they believe that patients are unable to receive or fully understand it. Similar dynamics emerged in the context of clinical trial recruitment.

Several physicians described filtering the information provided to patients according to their own perceptions of what was important to them and what they were capable of understanding.

"I look at which part will be most useful for them, and I tell them, 'Pay particular attention to this section' [of the participant information sheet]. I especially look for summary diagrams or timelines..." (Physician 11, male, medical oncology, 10 years of experience)

Another physician explained how time constraints influenced the amount of information provided, depending on their perception of individual patients' needs:

"Generally, I do not read [the participant information sheets] in detail. I have sometimes read them more carefully for a particularly anxious patient, so that I could explain everything properly. But generally speaking, they are long, and we have very little time. Given everything we have to do, we cannot afford to read them in detail." (Physician 15, medical oncology, 3 years of experience)

However, as Fainzang (2006) has shown, selective disclosure of information may also be influenced by social and cultural assumptions. Physicians may be more inclined to provide detailed information to patients whose sociocultural backgrounds resemble their own, while patients from less privileged backgrounds may receive less precise explanations.

Several physicians described spending less time explaining certain aspects of trials to patients whom they perceived as less demanding or less attentive to detail. Yet these supposedly individual

characteristics sometimes reflected broader social categorisations based on gender (such as an "anxious female patient") or social class (such as "men who drink and smoke" or "teacher-type patients").

"They do not care, and often—well, I have not had many cases—but they find it amusing. I have had patients say, 'I have never been there!' So their sample goes to Boston, and they say, 'Oh, I have never been there!' The idea that part of their body is going there amuses them. Are they concerned about protecting their data? Do they talk about it? No. To be honest, I think it depends on the population you are treating. The population I see is, frankly, mostly men who drink and smoke. Are you in ENT? No, urology. And they really do not care. It genuinely depends on the population." (Physician 11, male, medical oncology, 10 years of experience)

"It really depends on the patient's profile. And we say this, although we are being recorded... I am joking. But really, those 'schoolteacher types'... we say it, but it is true. They read everything word for word. You know, those kinds of profiles... Doctors, researchers, those are the people who will read it." (Physician 17, female, medical oncology, 40 years of experience)

Despite these limitations in information practices, physicians' accounts also suggested an awareness of the ethical norms and values associated with patient autonomy. This was reflected in expressions of hesitation or self-criticism during interviews, such as "Oh dear... no, not at all [I do not read them]", "And we say this, although we are being recorded... I am joking", or "I probably should not say this, but they are very rarely read."

Physicians nevertheless expressed concern for patients' informational needs and generally described themselves as available to discuss the trials and answer questions.

3.1.3. Physician influence: Perceived as inevitable, while responsibility remains largely unacknowledged

All interviewed physicians acknowledged exerting considerable influence on patients' decisions regarding clinical trial participation. This influence was primarily attributed to medical authority and the symbolic power of the "white coat". Recognition of physicians' expertise shaped the trust established within the physician–patient relationship. Consequently, patients rarely questioned their physician's decision to propose a clinical trial.

"When you represent a certain kind of medical authority, especially at a certain age, you do not have much difficulty convincing a patient to enrol in a trial—or not to enrol, if you see what I mean. Of course, this applies to most patients. It sounds terrible to say, but basically, you guide your patient because they are completely lost. So if you tell them, 'This could potentially be a good opportunity for you,' they will answer, 'I trust you, doctor.' You inevitably influence your patients." (Physician 5, male, dermato-oncology, 25 years of experience)

"Patients trust us, and that inevitably introduces a bias. Of course, we try to present things objectively, but the fact that we wear a white coat and that we are the ones proposing the trial is something that

cannot be disregarded in the decision the patient will make." (Physician 6, female, medical oncology, 2 years of experience)

Similarly, the way in which a trial was presented, together with the physician's enthusiasm and personal convictions, emerged as factors influencing patients' decisions.

Lexical analysis revealed the prominence of the word "chance" (*opportunity*), which appeared 50 times in physician interviews. Several physicians explicitly acknowledged that their own convictions strongly influenced patients' acceptance of trial participation. Some even considered "convincing" patients to be an integral part of medical practice, particularly when they believed that a trial represented a genuine therapeutic opportunity.

However, physicians also emphasised their intention to avoid exerting excessive influence. They reported refraining from repeatedly approaching patients who had declined participation, even when they considered the proposed trial clinically appropriate.

These accounts raise questions about the potential blurring of boundaries between clinical care and research, patients' therapeutic expectations, and the institutional discourse surrounding clinical trials.

The lexicometric analysis revealed a discrepancy between physicians' active role in the enrolment process and the way they described this role in their discourse.

Vocabulary associated with persuasion (*convince, influence*) was concentrated in Class 4, which was associated with informed consent and accounted for 34.7% of the classified text segments. This class was characterised by the overrepresentation of terms such as *read, sign, information sheet, take, information*, and *explain*.

These findings suggest that physicians recognised their active role in shaping patients' decisions. Their accounts went beyond the description of administrative procedures, such as reading and signing consent documents, and included an active process of persuasion.

However, this awareness was rarely accompanied by explicit ethical reflection. The 20 occurrences of the verb *convince* were consistently used in contexts in which persuading patients was presented as a natural or self-evident component of medical practice.

The term *influence* introduced a more reflective perspective, although its use appeared to differ according to gender: 56% of occurrences were associated with female physicians, compared with none associated with male physicians.

This limited explicit ethical reflection on physicians' influence was mirrored by the near absence of vocabulary relating to responsibility. The term *responsible* appeared only twice throughout the corpus, and in neither instance did physicians apply it to themselves. Thus, responsibility for patients' enrolment did not emerge as an explicitly acknowledged dimension of physicians' accounts.

The word *chance* (*opportunity*) appeared to fill this discursive gap by shifting the focus from responsibility to potential benefit.

Present in 50 text segments, it was predominantly used in impersonal expressions (36 of 50 occurrences), such as "It is an opportunity to be accepted into a trial", in which no identifiable individual was explicitly positioned as the decision-maker. Neither the physician's decision to propose enrolment nor the patient's decision to participate was foregrounded; instead, participation was presented as an opportunity that simply existed.

In a substantial minority of instances (14 of 50 occurrences, 28%), the word *chance* was associated with the action verb *enrol*. In these cases, the rhetoric of opportunity was explicitly connected to the physician's decision to enrol a patient, but the action was framed as offering a benefit rather than making a decision that entailed professional and ethical responsibility.

Overall, rather than indicating an active denial of responsibility, the corpus suggests a rhetorical diffusion of responsibility. Physicians acknowledged, and sometimes openly asserted, their influence over patients' decisions, but tended to present this influence as a natural and legitimate aspect of clinical practice. The emphasis on the "opportunity" represented by clinical trial participation appeared to overshadow the ethical responsibility associated with influencing patients' decisions to enrol in research.

3.2. The decision to participate: A process shaped by multiple influences

While physicians acknowledged that their own expectations regarding clinical trials could influence patients' decisions to participate, how do patients themselves experience this decision-making process? Patients facing prolonged illnesses and potentially life-threatening conditions often navigate complex care pathways. Being offered participation in a clinical trial therefore represents a significant event, and deciding whether to enrol involves multiple, interrelated factors. Rather than attempting to provide an exhaustive account, our analysis explores how patients' consent emerges through a process of shared construction, in which information, arguments, expectations and beliefs interact.

3.2.1. Clinical trial participation: An opportunity or a choice made in the absence of alternatives?

The rhetoric of opportunity previously identified in physicians' accounts was also prominent in patient interviews. Patients frequently perceived participation in a clinical trial as an opportunity, particularly following unsuccessful previous treatments. Clinical trials could thus represent a form of *technology of hope* [3], sometimes perceived as a final opportunity for recovery. Expressions such as "miracle treatment" and "tremendous hope" illustrated these expectations.

"It is a race against death, that is the reality of it. (...) There is still a 25 or 30% chance that it will come back, so we have to attack the cells at their source." (Patient E, male, 57 years, vocational qualification,

mechanical technician and security officer)

"The treatments I have received recently have not worked... That is why I am participating in the clinical trial. Perhaps it is an additional chance to try to recover." (Patient Q, female, 67 years, homemaker)

For these patients, participation in a clinical trial represented access to a new therapeutic option. However, previous treatment failures also shaped their decisions. Some patients perceived participation less as an opportunity than as a constrained choice arising from the absence of therapeutic alternatives. In such circumstances, the clinical trial appeared to be a default option.

"In any case, we do not really have much choice. We have to follow his advice. Well, 'have to'... we do not have many alternatives. If you offered me another, more effective treatment, I might choose that instead. [...] I think this is the only option available to treat me." (Patient G, male, 58 years, three years of higher education, financial development manager)

When clinical trial participation was perceived as the only viable therapeutic option, the decision was not so much to accept the trial as to reject the prospect of receiving no treatment. Patients described feelings of anxiety and urgency associated with cancer progression and the absence of alternative drug treatments, which contributed to their willingness to enrol.

"Being without treatment... because I can feel it, my lymph nodes have grown. So obviously, it makes me anxious, and I cannot wait to start treatment, even if there are side effects." (Patient O, female, 65 years, five years of higher education, primary school teacher)

Cancer was thus sometimes personified as an active threat exerting pressure on patients and accelerating their care trajectories. This perception was reinforced by the feeling that there was nothing left to lose, creating a perceived absence of choice between the possibility of recovery and death.

"Given my medical history (...) I was prepared to participate in any trial he wanted." (Patient A, female, 60 years, two years of higher education, accounting secretary)

Beyond perceptions of cancer and clinical trials, another major influence on patients' decisions emerged: their relationships with family members and significant others.

For some patients, family relationships encouraged participation, sometimes through explicit or implicit expectations to continue treatment. Surviving the disease became an objective closely linked to the desire to remain present for loved ones.

"I also adopted children in 2005, and I do not want to leave my wife alone with two kids. I did not adopt them just to miss seeing them grow up. [...] As for my own life, I have done my part, I have already had a good life... quite simply." (Patient E, male, 57 years, vocational qualification, mechanical technician and security officer)

"I have a wonderful wife who takes magnificent care of me. I have two children, aged 43 and 49, and I also have two absolutely wonderful grandchildren. If it works, and I really hope it does, I will have the chance to watch them grow up." (Patient J, male, 70 years, two-year technical higher education qualification, retired)

The influence of family relationships varied in intensity and could sometimes take the form of direct pressure.

One patient explained:

"My husband more or less 'forced' me, in quotation marks, because he absolutely wanted me to do it. He told me, 'You have to try, you have to try everything.'"

Yet the same patient expressed doubts about the meaning of further treatment and described a degree of resignation regarding her illness:

"I told him, I do not want to fight anymore. Well, I do want to fight, but why poison myself when none of the medications seem to..." (Patient U, female, 67 years, vocational qualification, retired)

In this situation, the patient's account suggests that her consent was strongly influenced by her husband's insistence on continuing treatment, despite her own reservations. Her decision to participate therefore raises questions about the extent to which consent was freely expressed.

Paradoxically, the absence of close family relationships could also encourage participation. In such cases, trial participation was sometimes perceived as an acceptable risk because patients did not anticipate that others would suffer the consequences of treatment.

"It is easier for me because there are no consequences for anyone else. I do not have children, I do not have that responsibility." (Patient C, female, 50 years, eight years of higher education, notary)

Ultimately, for some patients, participation in a clinical trial was experienced less as a freely chosen option than as an almost inevitable course of action. Whether driven by disease progression, the absence of therapeutic alternatives or family expectations, their decisions sometimes reflected a form of fatalism.

3.2.2. From meaning-making to consequentialist reasoning

Another major motivation emerged from patient interviews: the desire to feel useful. For some patients, participation in clinical research offered an opportunity to find meaning in their illness by contributing to the well-being of others.

"If our misfortune can contribute to someone else's happiness [...] if my illness can be useful to someone." (Patient A, female, 60 years, two years of higher education, accounting secretary)

This account illustrates how clinical trial participation may be understood as an act contributing to the common good. Patients frequently associated participation with scientific progress, using expressions such as "advancing research", "contributing to scientific progress", "serving science" or "helping future patients".

"It is a trial, and the more people who participate, the more conclusive the trial can be, the more the results can be analysed, and the more benefits it can bring to everyone." (Patient W, male, 32 years, five years of higher education, engineer)

Participation in a clinical trial may contribute to generating the scientific evidence required to determine the therapeutic value of a new drug or drug combination and inform decisions regarding its approval.

For some patients, the decision to participate therefore reflected a form of goal-oriented rationality, in which the anticipated consequences of an action were considered in relation to its intended objectives. Drawing on Max Weber's conceptual framework, this reasoning can be interpreted through an ethics of responsibility, in which individuals consider the potential consequences of their actions.

Participation was thus sometimes motivated by the prospect of benefiting future generations or contributing to scientific progress itself.

This reasoning could also emerge from patients' recognition that their own access to treatment had been made possible, at least in part, by previous clinical trials. Participation then became a form of reciprocity, an opportunity to contribute in return.

"Today, I can receive treatment because other people agreed to participate in trials before me. So if I can help other people in return..." (Patient W, male, 32 years, five years of higher education, engineer)

"If people had not contributed to developing these treatments and protocols... I think things would be much more difficult for me today." (Patient C, female, 50 years, eight years of higher education, notary)

Nevertheless, despite interview questions addressing altruistic motivations, many patients emphasised that their primary concern remained their own health. The justification of participation "for science" therefore had limits when personal risks were considered.

"I would not let myself be torn apart for science, but of course, if I can help..." (Patient A, female, 60 years, two years of higher education, accounting secretary)

"Advancing science... while hoping it will cure me!" (Patient Q, female, 67 years, homemaker)

For patients, participation therefore involved weighing potential personal risks and benefits alongside possible benefits for others. Their decisions reflected a form of consequentialist reasoning that incorporated both individual and collective outcomes.

Personal benefit and contribution to scientific progress were not presented as opposing motivations but rather as complementary considerations shaping the decision to participate.

Clinical trial participation could also help patients restore a sense of meaning and regain some control over their care pathway. Choosing to enter a trial represented a departure from the routine organisation of hospital care and could constitute a significant act of personal agency.

"When you are told you have this disease, you lose control over everything, absolutely everything. You are looked after by wonderful people, but you are being looked after, which means you no longer control anything. They decide on a protocol, they decide what is going to happen, and this was the first decision I made myself." (Patient C, female, 50 years, eight years of higher education, notary)

The altruistic argument of contributing to research and scientific progress was also reflected in physicians' accounts. Physicians similarly drew upon the vocabulary of usefulness to explain patients' motivations for participating in clinical trials.

"Patients are also pleased to participate because there is this sense of contributing to knowledge through clinical trials." (Physician 6, female, medical oncology, 2 years of experience)

"They often say, 'Yes, it is a good thing, this is how progress is made. I think about those who will become ill after me. If progress has been made, it is because research was conducted before.' People are generally quite altruistic in that respect." (Physician 18, female, medical oncology, 24 years of experience)

Physicians valued these motivations oriented towards the common good, consistent with their own perceptions of the scientific and social utility of clinical research.

"Research is not conducted to increase an individual's chances. Research is conducted to answer medical questions." (Physician 8, male, medical oncology, 25 years of experience)

However, beyond their commitment to the collective value of clinical research, physicians' own involvement in clinical trials was also embedded in professional dynamics. These included developing their scientific careers, maintaining access to innovation and strengthening the competitiveness and reputation of their institution.

"I tell patients two things. As a physician working in a highly specialised cancer centre [...] I consider it my responsibility to remain sufficiently informed and visible so that, whenever a trial provides access to an innovative therapy, a treatment de-escalation protocol or something similar, I am involved enough for our centre to participate. [...] I always tell them that this provides access to innovation and excellence in care. Of course, I make it clear that they are not obliged to participate, but I also explain that if patients do not take part in these trials, we will obviously be unable to make progress." (Physician 2, male, nuclear medicine, 20 years of experience)

Such statements may contribute to shaping patients' perceptions of clinical trial risks and benefits by emphasising the value of scientific innovation.

Beyond these considerations, trust emerged as a central factor in understanding patients' willingness to participate in clinical research.

3.2.3. Decision-making based on trust rather than written information

Trust was a recurring theme in both patient and physician interviews.

According to Marie-Christophe Boissier's article, *Trust in the physician–patient relationship* [13], trust encompasses a set of beliefs and expectations regarding physicians' behaviour, including competence, compassion, confidentiality, reliability, honesty, loyalty and communication skills.

These dimensions were reflected in patients' accounts and frequently served to justify delegating decision-making to physicians. The reputation and prestige of both the professionals and the cancer centre also functioned as sources of authority.

"You have to deal with it and trust the people who know more than you do." (Patient D, male, 65 years, vocational qualification, butcher)

"We need to discuss things, and then I trust them. I trust [the centre], I trust Dr X. I was told he is an outstanding specialist. [...] As someone told me, at [the centre], they are all top of their class." (Patient E, male, 57 years, vocational qualification, mechanical technician and security officer)

Patients referred to physicians' competence, reliability and communication skills as reasons for placing their trust in them. This trust appeared to play a substantial role in their acceptance of clinical trial participation.

Trust was also reinforced by the duration of the therapeutic relationship. Clinical trials were frequently proposed following previous treatment failures, meaning that patients had often been receiving care from the same medical team for a considerable period. The trust established throughout this care pathway thus provided a foundation for accepting participation.

"I feel very well cared for. I have complete trust in Dr X." (Patient O, female, 65 years, five years of higher education, primary school teacher)

This relational dimension has been examined by Alexandre Jaunait in his work on the physician–patient relationship. He argues that patients may voluntarily choose to entrust therapeutic decisions entirely to their physicians, particularly when their health condition makes the cognitive and emotional burden of decision-making difficult to bear. Patients may prefer to devote their remaining time and energy to their families rather than engage in complex therapeutic deliberations [21].

Our findings similarly suggest that trust in physicians plays a central role in patients' decisions to participate in clinical trials.

This trust was also associated with limited engagement with written participant information sheets. Seven of the 28 patients interviewed reported not reading the information sheet before signing the consent form, while several others described reading it only partially, selectively or after signing.

As with physicians, patients' reading practices were highly variable. Several factors may explain this variation.

First, the length and complexity of participant information sheets may discourage careful and comprehensive reading, creating a gap between the intentions of those drafting the documents and patients' actual understanding.

The scientific, medical and legal terminology used in these documents can make them difficult to understand. Many patients perceived the information sheet primarily as an administrative requirement rather than a meaningful source of information.

Fainzang (2006) similarly emphasised that written consent is often perceived as a formality, with linguistic complexity reinforcing the impression that such documents are intended primarily for institutions rather than patients.

"It is enormous. And there are two huge documents. I did not even understand what each one was for; there are two of them. [...] And then you have to understand the terminology." (Patient Q, female, 67 years, homemaker)

"It is quite tedious. So for someone who does not have a strong scientific background, it may be rather overwhelming, and a summary would indeed be necessary." (Patient N, female, 67 years, six years of higher education, pharmacist)

The IRaMuTeQ analysis identified a structural opposition between two main dimensions of patients' discourse: the **physician's proposal of the treatment protocol**, characterised by vocabulary relating to treatment, oncologists and clinical follow-up; and the **patient's engagement with the information received**.

The latter dimension comprised two distinct lexical registers: active engagement with written information, associated with female participants, and a more hesitant register characterised by questioning and uncertainty, whose associated participant characteristics require further investigation.

No statistically significant association was identified between reading the participant information sheet and age, socioeconomic category or trial phase. Although these findings must be interpreted cautiously given the limited sample size, they suggest that relational factors, such as trust in physicians and the

way trial participation is proposed, as well as individual characteristics not measured in this study, may contribute to patients' engagement with written information.

Although no statistically significant association between socioeconomic category and reading practices was observed, the qualitative analysis suggested differences in patients' understanding of and perceived usefulness of participant information sheets according to their educational and social backgrounds.

When the physician–patient relationship was particularly asymmetrical, notably among patients with lower levels of formal education, oral explanations provided by physicians often constituted the principal source of information.

Such reliance on physicians may reinforce a situation in which consent functions primarily as an administrative validation rather than as the outcome of a genuinely informed deliberative process.

Conversely, patients with higher educational attainment sometimes described reading information sheets carefully and critically.

Patient C, a 50-year-old woman with eight years of higher education working in the legal profession, explicitly reflected on the role of her educational and professional background in enabling her to understand complex information documents.

"What is particular about this kind of information sheet is that, once again, there are words that are completely incomprehensible to ordinary people, and I certainly include myself among them. [...] For some people, and I do not mean this in an unkind way, I can see this through my own profession as well, there are words that we consider simple but that are not simple for everyone. [...] It is not that I am more intelligent than other people, but perhaps I have had more education, and that education enables me to understand those words." (Patient C, female, 50 years, eight years of higher education, notary)

However, educational attainment alone did not explain active engagement with written information.

Patients with lower levels of formal education also described mobilising other resources to obtain information, sometimes independently of healthcare professionals.

"The information is very precise. It is not simple, because there are some rather technical words. Too many, even. You understand them, even though you are not a doctor, but they are not simple. Sometimes... Google! To find out what they mean." (Patient E, male, 57 years, vocational qualification, mechanical technician and security officer)

Trust in physicians therefore did not necessarily imply passivity or a lack of interest in clinical trials or patients' own care pathways.

Several patients reported actively seeking information beyond that provided by physicians or contained in participant information sheets.

"Oh yes, I have researched it extensively. Even nutrition and... everything related to cancer, I have looked into it very thoroughly. [...] I had also done some research. Yes, in the United States. It was approved in 2012, I think." (Patient G, male, 58 years, three years of higher education, financial development manager)

Patients' progressive socialisation into the experience of illness may also facilitate their appropriation of medical terminology throughout their care trajectories, as discussed by Carricaburu and Ménoret (2005).

Over time, patients develop knowledge and practical skills that enable them to better understand their condition, interact with healthcare professionals and adapt their behaviour to medical recommendations.

This learning process, involving both adaptation and the appropriation of medical knowledge, may influence not only disease management but also how patients approach decisions concerning participation in clinical research.

"There are words and terms that not everyone can know, and they can be quite difficult to read. But once you start becoming familiar with the medical system, you manage." (Patient U, female, 67 years, vocational qualification, retired)

Patients therefore undertake substantial work that often remains invisible.

This work extends beyond following medical instructions and encompasses the tasks and efforts required to manage the demands of treatment and research participation, including uncertainty about the trial and its possible consequences for everyday life and health.

This *patient work* [22] constitutes a fundamental dimension of the informed consent process. It may involve reading an information sheet of approximately 40 pages, seeking clarification from healthcare professionals, making telephone calls, searching the internet and reorganising daily life to accommodate a demanding trial protocol.

Such efforts to obtain information may also lead patients to actively choose which healthcare professionals they wish to trust.

"I trust the doctor who is looking after me. Or, if I do not trust them, I ask to change doctors, because trust really is very important. That actually happened with my surgery. The first surgeon I saw did not communicate well with me because he broke the news very abruptly, and I became rather defensive. So I changed surgeons, and after that everything went very well." (Patient G, male, 58 years, three years of higher education, financial development manager)

Trust and information-seeking should therefore not be understood as opposing practices, but rather as potentially complementary dimensions of patients' decision-making.

For some patients, trust in their physician was sufficient to justify participation, while for others, acquiring additional knowledge about their disease or the proposed treatments strengthened their willingness to enrol in a clinical trial.

Nevertheless, the readability and accessibility of participant information sheets remain important concerns, raising questions about the potential reproduction of social inequalities in health and informed decision-making.

4. Conclusion

Our analysis of informed consent in clinical trials highlights the complexity of a process that cannot be reduced to an individual, purely rational decision. Rather, consent emerges as a collective and dynamic process shaped by organisational, ethical and relational factors. Physicians operate within a research environment characterised by competition between institutions and increasing pressure to innovate. Their involvement in clinical trials is influenced by professional networks and considerations relating to feasibility, scientific relevance and potential therapeutic benefit. Patients, in turn, may perceive trial participation either as an opportunity or as a choice made in the absence of alternatives. Their decisions are shaped by hopes of recovery, a sense of urgency and the desire to contribute to scientific research. Informed consent therefore develops within a context marked by patient vulnerability, the constraints imposed by illness and the institutional dynamics of clinical research.

Physician influence emerges as a central component of this process and is sometimes regarded as necessary, particularly in challenging therapeutic situations. Nevertheless, this influence raises important ethical questions concerning informed consent, patient autonomy and the boundaries between providing information, persuasion and supporting decision-making. Trust plays a particularly important role in this relationship. Medical expertise, the explanations provided and the support offered by physicians contribute to patients' sense of security and shape decisions that are closely linked to the information they receive.

Given the multiple factors influencing consent, particularly the physician–patient relationship, therapeutic expectations and patients' social circumstances, to what extent can consent to clinical trial participation truly be considered free and informed? How might the consent process be improved? Should current approaches to providing information to patients be reconsidered?

Our analysis of patient interviews revealed that the vast majority had reflected on their participation before signing the informed consent form. None reported feeling that they had yielded to pressure, and none used expressions such as "guinea pig" or "experimental subject". All demonstrated some degree of awareness of the potential benefits and risks of participation, although their willingness to accept these risks varied according to their perceptions of their health status and therapeutic prospects. Most patients did not base their decisions on the investigational drug or its mechanism of action, nor did they seek detailed information about these aspects. Instead, they placed their trust in their physicians, believing that the proposed trial represented the most appropriate therapeutic option for themselves and their families. Some deliberately chose not to receive certain details about the protocols because they considered such information anxiety-provoking.

These findings highlight the substantial responsibility borne by physicians when deciding whether to offer patients participation in a clinical trial. The way physicians present a trial, explain its potential benefits and risks, and communicate its relevance both to the individual patient and to clinical research more broadly can strongly influence patients' willingness to participate. Physicians' enthusiasm and personal conviction frequently play a decisive role in this process.

The responsibility of physician investigators also extends beyond the moment of consent. Upstream, they are responsible for selecting the clinical trials in which they intend to enrol patients; downstream, they are responsible for monitoring participants and managing trial discontinuation when the anticipated benefits are not achieved. If trial selection has not been carefully considered before recruitment, the quality of informed consent may be compromised, particularly if physicians lack sufficient knowledge of the protocol to explain it adequately.

Physicians therefore bear a considerable ethical responsibility in identifying the most appropriate trial for each patient, taking into account the anticipated benefit–risk balance and the potential consequences of participation for quality of life. Although sponsors and research ethics committees, including the French *Comités de Protection des Personnes* (CPPs), have essential responsibilities in ensuring the scientific and ethical acceptability of clinical research, they do not participate directly in individual recruitment decisions or in the therapeutic relationships established with patients and their families. The physician's responsibility in these individual decisions is therefore particularly significant.

Ultimately, consent to clinical trial participation appears less as an isolated, entirely independent decision than as the outcome of a co-constructed process shaped by multiple influences. While medical authority continues to play a major role in patients' decisions, our findings also highlight the importance of relational influences, particularly those exerted by family members, and moral considerations associated with contributing to scientific progress. Understanding these influences is essential to promoting consent processes that genuinely respect patients' autonomy while acknowledging the relational and contextual dimensions of decision-making.

Rather than undermining patient autonomy, the relational nature of consent calls for a broader understanding of autonomy, one that acknowledges the influence of trust, vulnerability and interpersonal relationships. Within this framework, physicians have a particular ethical responsibility not merely to obtain consent, but to create the conditions in which patients can make decisions that reflect their own values, preferences and priorities.

Declarations

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

BC designed the study. DA, NCH, JPD and IK provided critical input on study design and interpretation. BC conducted the patients and clinician interviews and contributed to data analysis. DA and BC drafted the manuscript. All authors revised the paper for important intellectual content and approved the final version of the manuscript.

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Ethics approval and consent to participate

The study adhered to the Declaration of Helsinki. Ethical approval was obtained from the *Comité Éthique de la Recherche* of the *Université Fédérale de Toulouse* on February 23, 2023 (reference no. 2023 – 628). All participants provided written informed consent prior to inclusion in the study.

Clinical trial number: not applicable.

Data Availability

The datasets generated and analysed during the current study are not publicly available due to confidentiality considerations and the potential risk of participant re-identification. Anonymised data may be made available from the corresponding author upon reasonable request, subject to applicable ethical and data protection requirements.”

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