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Ethical and Integrity Challenges in Accelerated Clinical Trials: Perspectives from Key Stakeholders

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Abstract

During major global health emergencies, speeding up clinical trials for new drugs and vaccines helps deliver solutions more quickly, yet it also creates notable difficulties in research ethics and scientific integrity. It is essential to identify and address these difficulties to safeguard the well-being of those participating in studies and uphold fairness and credibility in scientific work. The current study examines the specific research ethics and integrity issues that arise when clinical trials are conducted at an accelerated pace. A qualitative approach was adopted, relying on semi-structured interviews conducted remotely with individuals who play central roles in overseeing, planning, carrying out, and disseminating clinical trials. These interviewees were seasoned professionals drawn from academic settings, pharmaceutical firms, non-governmental bodies, and national and international regulatory agencies and publishing outlets. They were chosen via purposive sampling techniques. The interviews were conducted online from April to July 2023. Resulting transcripts underwent thematic analysis that combined deductive and inductive coding strategies, supported by the MAXQDA software package. Key challenges that surfaced were: heightened forms of longstanding issues involving the enrolment of participants and the process of obtaining informed consent; inadequate direction coupled with heavy demands placed on ethical and scientific evaluation procedures; the absence of well-defined approaches and unclear accountability when communicating with the wider public; and weak levels of teamwork, insufficient coordination, plus fierce rivalry over research funding and necessary support systems among different research teams. Among the proposed measures were: involving patients more actively at every stage of the accelerated trial pathway, beginning with planning and extending through execution; equipping Research Ethics Committees with specialized preparation focused on fast-tracked studies; advancing clear and open dialogue aimed at the general public; building stronger cross-border partnerships; and transitioning from acceleration models driven primarily by commercial interests to ones that place people at the center. The outcomes emphasize the need for broad-ranging reforms in how accelerated clinical trials are managed. These reforms need to encompass enhanced transparency within clinical research activities and better global-level coordination. Such steps would help address concerns about ethics and integrity, while maintaining high standards of scientific quality, preserving public confidence, and supporting equitable outcomes.

Keywords: Research ethics, Research integrity, Responsible conduct of research, Clinical trials, Pandemic

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Introduction

Global health emergencies triggered by infectious disease outbreaks have accelerated the development of medicines and vaccines through fast-tracked clinical trials [1-3]. In addition, such accelerated trials have been favored because they can prolong periods of market

exclusivity and increase overall efficiency in the pharmaceutical field [4, 5]. Prominent cases involve the testing of the Ebola virus disease (EVD) vaccine in response to the 2013–2016 epidemics across West Africa [1, 2], as well as investigations into two therapies targeting drug-resistant tuberculosis (XDR-TB) once authorities labeled it a critical public health danger back in 2006 [3, 6]. In general, accelerated clinical trials are those that complete their development cycle in notably less time than standard trials, regardless of what drives the quicker timeline. Shortening occurs through streamlined approval routes with regulators, swifter volunteer enrolment, flexible study frameworks, or concurrent production and research phases. The arrival of the COVID-19 pandemic sparked a dramatic increase in the volume of these fast-paced trials seeking to generate workable treatments and preventive shots [7]. A substantial portion incorporated cutting-edge methods—including multi-arm, multi-stage, or adaptive platform designs—or began mass-producing various vaccine options even before receiving official clearance [8]. Even though these compressed timelines offer clear gains for multiple parties, they often raise weighty ethical and integrity issues, erode public confidence, and sometimes worsen disparities in who can access healthcare [8].

Understanding the research ethics and integrity-related hurdles in accelerated clinical trials is crucial for protecting participants in studies and ensuring that new scientific knowledge meets standards of excellence and reliability [9, 10]. Research integrity encompasses the professional expectations and practices that ensure the soundness and reliability of study findings [11, 12]. By contrast, research ethics focuses on value-based questions that arise either before or during research [12]. Such questions commonly relate to protecting and honoring participants' independence, as well as matters of fairness concerning which groups are included in research or who ultimately benefits from the resulting discoveries [13, 14]. Elements like trust and fairness within both research integrity and research ethics can prove especially sensitive under accelerated conditions. For research integrity, the element of trustworthiness serves as a core foundation that encourages involvement and continued societal support for clinical investigations, especially when haste and uncertainty are prevalent [10]. In research ethics, fairness emerged as a central theme, beginning with the Belmont Report [13] and further developed in later revisions of the Declaration of Helsinki. Its relevance grows in accelerated settings, as certain demographic or regional communities may easily end up sidelined [8].

A range of ethical and integrity-related problems tied to clinical investigations and trials amid the COVID-19 outbreak has already surfaced in editorials, eyewitness accounts, and formal publications [15-22]. Reports in these works point to difficulties such as: complications around securing informed consent and overseeing participants that stemmed from restrictions imposed for public health reasons during the crisis [22, 23]; imbalances in how research assets and advantages were shared out [18, 19]; hurried assessments performed by Research Ethics Committees (RECs) when facing time-critical scenarios [16]; overlapping projects and rivalry for volunteers that produced limited or non-diverse participant groups [15]; shortfalls in openness together with tendencies toward selective publishing in COVID-19 work funded by drug manufacturers [7]; or the routine leaving out of at-risk or underrepresented communities from COVID-19 trial cohorts [24-26].

While direct involvement has helped spotlight some of these concerns, a noticeable shortfall persists in original, data-driven investigations that specifically examine ethics and integrity issues arising from accelerated clinical trials as they unfold in real European settings. In particular, there is limited attention paid to the perspectives of professionals who handle the regulation, planning, execution, and release of such trials. Earlier work has tended to focus on integrity issues reported by health researchers in general—not restricted to trials—within a single organization during the COVID-19 period [27], or on possible remedies for research obstacles encountered in epidemics and pandemics beyond COVID-19 [23]. Through this project, we intend to close that gap by providing an in-depth look at the research ethics and research integrity challenges associated with speeding up clinical trials, drawing directly on the experiences and opinions of experts in the field.

Materials and Methods

Study design

The investigation followed a qualitative interview format. Material gathered during the process supported two distinct projects: the one reported here and a separate upcoming study by van Eck *et al.*, which focuses on identifying the main factors driving trial acceleration in Europe. Semi-structured interviews were carried out by CPP and LE, both based in Amsterdam, The Netherlands.

All sessions took place remotely via online platforms between April and July 2023 and targeted professionals actively engaged in the regulation, design, conduct, and publication of clinical trials.

Participant recruitment

Recruitment relied on purposive sampling to identify professionals working in Europe who hold key roles in the regulation, design, implementation, and publication of clinical trials. Potential participants were approached through the authors' wide-ranging professional connections, which encompassed various European research initiatives and both previous and current joint projects. Snowball sampling was also employed, whereby interviewed individuals were invited to recommend and contact other suitable experts.

In this project, key stakeholders were defined as professionals with specialized knowledge in the regulation, design, implementation, and publication of clinical trials. The aim was to assemble a diverse group of experts from different organizations active in these domains. Included were individuals connected to scientific journals, clinical investigators, policy consultants, advisors on clinical trial development, specialists in bioethics, staff from pharmaceutical firms and non-governmental organizations (NGOs), personnel from the European Medicines Agency (EMA), officials from National Competent Authorities across several European nations, as well as representatives from the World Health Organization (WHO) and the European Commission. Although recruitment succeeded for most categories, no participants from the WHO or the European Commission could be secured despite persistent attempts. A full description of the final sample makeup and participant profiles is presented in the Results section.

Every prospective participant received a standard invitation letter outlining the purpose of the research. Those who agreed to join completed a signed informed consent document and filled out a brief demographic and expertise questionnaire. To help ensure all interviewees shared the same understanding of the phrase 'accelerated clinical trials', a brief standard definition was provided both ahead of and during the sessions:

Accelerated clinical trials are clinical trials with a shorter clinical development time than average, regardless of the underlying cause of that acceleration. This type of trial has shortened their time through expedited regulatory processes, faster recruitment, adaptive trial designs, or parallel manufacturing and trial activities.

Data collection

All interviews were conducted as semi-structured video calls. LE performed 14 of them independently, while the remaining 11 were carried out jointly with CPP. Sessions were planned to last around 30 minutes each and were recorded only after participants had granted both spoken and written approval. The discussion followed an interview guide containing questions on the reasons for trial acceleration, as well as related ethical and integrity concerns. Because the guide was prepared for two connected studies—one exploring drivers of acceleration in Europe and the present one examining ethics and integrity issues—it addressed both themes. Some questions targeted drivers, while others focused on ethical and integrity difficulties.

Nevertheless, participants raised ethics- and integrity-related points throughout the conversations. Consequently, the full set of responses was examined for this paper rather than limiting the analysis to responses to the dedicated ethics and integrity questions. When addressing challenges linked to accelerated trials, experts were prompted specifically about social and ethical issues, the reliability of study outcomes, and levels of public confidence. They were also encouraged to mention any additional topics they considered relevant to the ethical or integrity aspects of fast-tracked trials. Before final use, the guide was pilot-tested with a postgraduate student and a global health researcher employing the 'thinking-aloud' technique [28] and then adjusted based on feedback.

Data analysis

Recordings were converted into written transcripts using the GDPR-compliant artificial intelligence service Amberscript (www.amberscript.com). LE and/or CPP subsequently reviewed each transcript for correctness. The tool uses encryption and follows strict security procedures; all files were permanently removed from the platform after transcription, in keeping with both institutional policies and platform requirements. Analysis for this study was performed in MAXQDA software and followed a thematic approach designed to reveal major cross-cutting patterns. Coding combined deductive and inductive elements [29]. An initial set of deductive codes was created, drawing on research ethics

themes from the Declaration of Helsinki [30] and research integrity themes from the Singapore Statement for Research Integrity [11]. CPP and GI first applied this code tree to 10 interviews. Additional subcodes were then developed inductively to better reflect the experts' practical experiences with ethics and integrity challenges. The revised coding structure was applied to all transcripts, and any newly emerging inductive codes or differences in interpretation were discussed repeatedly between CPP and GI. After completing the review of all 25 interviews, deductive codes that had not appeared in the material were dropped. The final coding framework was reviewed together by CPP, GI, and NE. CPP then organized related codes into broader analytical themes that captured the ethics and integrity challenges reported by professionals, aiming to reduce redundancy. These themes were further discussed and refined in collaborative team sessions.

Ethics approval

The team conducted an online self-assessment of ethical compliance using the dedicated platform of the Ethics Committee of the Faculty of Science (BETHCIE) at Vrije Universiteit Amsterdam. This tool asked a set of questions to check alignment with the Faculty of Science's Code of Ethics for research involving human participants. The project fully satisfied the code's requirements, so no further formal review by BETHCIE was necessary. Because the study would collect personal details and the researchers would know who the participants were, particular attention was given to creating a detailed research data management plan. In addition, all participants signed an informed consent form.

Positionality and reflexivity

A European research group based in the Netherlands carried out this project while actively contributing to several EU-funded initiatives. The lead author, with training in biomedicine, bioethics, and public health, conducted the work as part of her PhD research, which examines epistemic injustice in research ethics and integrity. She and her supervisors are based in the Department of Ethics, Law, and Humanities at Amsterdam University Medical Center (UMC). The rest of the team is based at the Center for Tropical Medicine and Travel Medicine at the same university and supports international efforts to enhance clinical research standards. The team's research interests and their involvement in European projects influenced the development of the study questions, facilitated contact with interviewees, and shaped the interpretation of findings. This proximity to research ethics (RE) and research integrity (RI), along with the team's specialized knowledge, is evident in the article's specific focus.

Results and Discussion

Participants demographics

Twenty-five people accepted the invitation and joined the study, out of 192 individuals contacted. The final group included five specialists from major pharmaceutical companies, three from the EMA, three from various national competent authorities (NCAs), and thirteen others who were seasoned global health researchers, bioethics specialists, policy consultants, staff from different non-governmental organizations (NGOs), or editors at academic publishing outlets **(Table 1).** Most participants [20] had over 10 years of experience in clinical trials, and 16 held a PhD **(Table 2).** At the time of the interviews, the participants were located in Europe, the United States, or Canada, but all had professional ties to European organizations, research centers, or collaborative projects.

Table 1. Participants categorized per stakeholder group

Stakeholder category	Number of participants	KOL role specifications	Number of participants
Key opinion leaders (KOLs)*	13	Senior scientific journal editor	1
		Senior health sciences researcher	1
		Policy advisor	8
		Clinical trial development consultant	1
		Bioethics specialist	4
		Non-governmental organization (NGO) representative	2

Pharmaceutical industry representatives	6	—	—
European Medicines Agency	3	—	—
National competent authorities	3	—	—

1. *The breakdown of the key opinion leaders is specified in columns 3 and 4
2. **Many key opinion leaders fulfilled multiple roles

Table 2. Participants demographics. From: Research ethics and integrity challenges in accelerated clinical trials, an interview study

Demographics	Category	No. of participants
Gender	Male	16
	Female	9
Age category* (in years)	31–45	9
	46–60	8
	60+	6
Highest level of education*	Master's degree	8
	PhD	16
Relevant work experience (in years)*	1–3	1
	5–10	3
	10+	20
Country of current employment *	The Netherlands	8
	United Kingdom	4
	Switzerland	3
	Belgium	2
	Bulgaria	1
	Czechia	1
	France	1
	Greece	1
	United States	2
	Canada	1

1. Two participants did not or only partly completed their questionnaire

Themes

Four main themes emerged regarding ethics and integrity difficulties in accelerated clinical trials:

1. Familiar ethics and integrity challenges amplified.
2. Pressure and gaps in scientific and ethics review.
3. Missing strategies in public communication.
4. Collaboration, coordination, and competition.

Each theme is described in the sections below. Each theme also includes suggestions for addressing the issues proposed by the experts.

The experts held differing opinions on the extent to which ethical and integrity issues arise in accelerated clinical trials. Bioethicists and policy advisors tended to spot these issues quickly. In contrast, researchers, pharmaceutical company staff, and representatives of national competent authorities often had more difficulty naming specific challenges associated with faster timelines. Still, all experts agreed that familiar ethical and integrity problems encountered in ordinary clinical trials become more pronounced when studies are rushed. These included difficulties with recruiting and including suitable participants and obtaining proper informed consent.

Recruitment and inclusion of participants

Several experts noted that concerns about sample diversity and the frequent exclusion of vulnerable groups — such as children and pregnant women — become even more serious in accelerated clinical trials. Including these populations demands extra ethical scrutiny, which can slow down review processes. Because of this, according to Expert 5 (a researcher and policy advisor), such groups are included even less often in fast-tracked studies.

Informed consent

Experts observed that running accelerated trials during public health emergencies can put greater pressure on investigators to convince patients to participate in the research. One participant remarked:

"We still need to obtain proper informed consent. However, we cannot judge how persuasive the researcher is. From our position, we have no direct view of what happens. We do know that certain investigators are better at enrolling patients […]. This largely depends on the way patients receive information about the trial. But that process is controlled by the investigator. So we remain quite distant from knowing the actual situation. We do ask about their approach during discussions. How do they explain the trial to patients? What methods do they use? And there are clearly big differences between them." (Expert 20, professional working at a large pharmaceutical company)

Some experts also noted additional complications with informed consent in decentralized COVID-19 trials that relied on digital procedures. Although electronic consent is faster, one ethicist and policy advisor worried that the lack of personal contact between participants and the research team could reduce participants' real understanding of the study.

Recommendation: patient-centered trials

Several experts stressed that involving patients and research participants from the very beginning and throughout all stages of the trial — including study design — is vital to addressing ethical and integrity challenges in accelerated clinical trials. This approach could lead to trials that are both quicker and more effective, while also increasing preparedness and openness. According to experts from clinical trial advisory and regulatory roles, there is a strong need to move away from standard practices. Truly efficient accelerated trial design should include listening carefully to patients' views at every step of the clinical research process, from planning and execution to assessing outcomes:

"We should start working together with patient organizations much sooner so they can help set the right trial goals, choose suitable endpoints, and identify the appropriate target group. Quite often, companies claim their products meet an unmet medical need, but this is not always accurate. When they propose a trial design or particular endpoints, these are not necessarily the most important ones for the people who will ultimately use the treatment." (Expert 19, professional working at a National Competent Authority).

Theme 2: pressure and gaps in review

Many experts expressed serious concerns about the ethical and scientific review procedures for accelerated clinical trials that began during the COVID-19 pandemic. Research Ethics Committees (RECs) experienced intense pressure. They frequently had to adapt their review methods on the spot because of tight deadlines, insufficient guidance, and limited familiarity with rapid-review processes, innovative study designs, and unfamiliar methodological approaches. For instance, a bioethicist and policy advisor based in Europe recalled a situation in which trial protocols were evaluated only by the committee chair at a university, rather than the usual two reviewers plus a chair. This change occurred because of severe time constraints, the absence of clear instructions, and a sudden surge in the number of submissions:

"I believe ethics committees must receive proper instructions on fast-track methods since we have to react swiftly during a pandemic […]. When the crisis started, nobody really understood how to handle it. The approach was to create a system that would prioritize COVID-19 studies and expedite reviews. Instead of sending protocols to the standard two reviewers and a chair, they sometimes went only to the chair or to the chair and one reviewer. But even then, we must ensure nothing important is overlooked. Speeding things up should not mean ignoring any of the necessary ethical aspects." (Expert 9, Bioethicist and policy advisor).

Experts further highlighted the frequent absence of a distinct scientific review separate from the ethical review in accelerated studies. At the European level, according to one bioethicist and policy advisor, it remains unclear which body is responsible for examining the technical and scientific aspects of trial protocols. In many cases, without an independent reviewer for methodological questions, these elements receive inadequate attention because RECs often lack the necessary expertise or sufficient time. This problem was especially noticeable during the COVID-19 pandemic, when committees faced a much higher volume of protocols and extremely limited time for thorough evaluation.

Recommendation: improving skills and defining responsibilities

A few experts proposed practical steps to strengthen RECs' knowledge and capabilities. Two specialists — one from the EMA and one from a National Competent Authority — recommended additional training for committee members and the creation of specific procedures for crises. They also suggested appointing a European-level REC advisor to serve as a central point of reference during emergencies. They encouraged closer cooperation among RECs with different areas of expertise across Europe. Regarding scientific review, one bioethicist and policy advisor proposed introducing rules requiring sponsors to evaluate the methodology and practicality of studies across Europe. Such a requirement could improve quality not only in accelerated trials but also in conventional clinical trials.

Theme 3: missing strategies in public communication

When discussing public confidence in accelerated clinical trials, almost every expert identified communication as a major issue in research integrity. They stressed that effective communication is vital if scientific progress is to benefit society. If information is not conveyed clearly, people may fail to understand why certain medical products can be developed more rapidly, undermining trust. The main difficulties identified were the public's grasp of accelerated processes and the unclear division of responsibilities for science communication.

Public understanding of accelerated procedures

Experts explained that shortened clinical trial timelines affect how ordinary people view the reliability of research outcomes. While they generally accepted that speeding up trials is reasonable during emergencies, they understood why members of the public might feel uneasy when explanations are inadequate. During the COVID-19 pandemic in particular, some experts noted that it was understandable for people to wonder why vaccines were developed and approved far more quickly than for other illnesses. One bioethicist and policy advisor emphasized that the accelerated COVID-19 trials were in fact safe, and that any perception of increased risk stemmed from poor communication rather than actual safety problems:

"A large part of the issue comes down to communication and helping people understand what has changed and why the trial moved faster. Many people mistakenly believe that shortcuts are being taken or that there is insufficient supporting data. They worry that the first people to receive a product with emergency authorization are essentially test subjects […]. In my view, this was a failure of communication, not a failure of ethics." (Expert 8, Bioethicist and policy advisor).

The ambiguous responsibility of science communication

The experts concurred that maintaining public trust in science is a shared duty involving industry, the media, governments, and other stakeholders, yet the exact roles in accelerated trials are often undefined. Most believed that the absence of clearly assigned responsibilities for sharing results leads to weak or inconsistent communication strategies. One global health researcher noted that companies developing COVID-19 vaccines often did a poor job of explaining their development process, which fuelled public reluctance to accept the products. Experts also noted that academic publishers lacked clear communication approaches when questionable studies appeared, such as the later-discredited hydroxychloroquine trials during the pandemic. Additionally, some experts observed that political leaders can significantly affect trust in science. When politicians fail to firmly reject misinformation or when the public harbors broad distrust toward government figures, the overall quality of scientific discussion in society suffers:

"A great deal of the skepticism toward science has little to do with the research findings themselves. It is shaped instead by the wider social and political environment in which the science is conducted and shared. If people distrust the government, then scientists alone can achieve only so much." (Expert 10, experienced global health researcher and policy advisor).

Recommendation: honesty, transparency, preparation, and public involvement

The experts' suggestions for strengthening public confidence in accelerated clinical trials varied considerably. They ranged from upholding core moral principles such as honesty and transparency to more concrete, practical measures.

Honesty and transparency

Several experts highlighted honesty and transparency as fundamental principles for building trust. Following these principles also involves helping the public better

understand the scientific process and the fact that scientific knowledge continues to develop over time:

"I believe being honest when communicating with the wider public is vital. People need to understand how vaccines and medicines are actually developed, what kinds of checks and ethical safeguards are included in clinical research […]. We also have to be straightforward: we saw this at the start of the COVID pandemic — when trial results are first published, that is not the final story. More data will emerge once the products are rolled out. We will keep learning afterward, and it must be made clear that knowledge will keep advancing." (Expert 2, senior editor at an academic publishing group)

Public and patient involvement (PPI)

Experts called for clinical research to be more open, inclusive, and accessible to strengthen the trust relationship between the scientific community and the general public. Involving the public was a repeated suggestion. Practical steps proposed included: providing greater financial support for public awareness initiatives and patient advocacy organizations; hiring communication specialists at every research institution; and including patient representatives in key decision-making processes.

Theme 4: collaboration, coordination, and competition

Experts examined the problems caused by weak international coordination and collaboration, as well as intense competition, and explained how these factors can directly create injustices in research. In emergencies, the absence of strong global coordination, combined with strong financial motivations, urgency, and competitive pressures, often results in scattered efforts, repeated studies, and the worsening of existing inequalities.

Fragmentation and duplication of research efforts in COVID-19

Some experts with backgrounds in ethics or in working for national and international regulatory bodies discussed the issue of duplicate clinical trials. During the COVID-19 pandemic, the rush to discover effective treatments, coupled with competition and poor coordination, led to many overlapping studies. One bioethicist and policy advisor described this situation as a 'scandal' based on direct experience:

"I spent a lot of time in the hospital, and one of the first things I noticed was two separate trials running at the same time — one organized by the hospital itself and the other by the Ministry of Health. They were competing for the same patients. This seemed completely irrational to me because we were wasting time and repeating work. There were small differences between the studies, but overall, the entire COVID situation became a scandal. Hundreds of trials were carried out that served no real purpose — many driven by people chasing funding and wanting their names on publications. It was an enormous waste of resources, time, and money, and it delayed useful results for everyone. Just look at the whole chloroquine situation." (Expert 15, Bioethicist and policy advisor)

When research efforts become fragmented, competition arises over limited resources and support systems — including patients, staff, facilities, administrative processes, and equipment. This can result in inefficient resource use and studies that lack sufficient statistical power. During the COVID-19 pandemic, experts noted that it posed a research integrity problem by diverting effort to low-quality studies and raised research ethics concerns by producing unreliable findings and, at times, compromising patient safety. One bioethicist and policy advisor gave the example of accelerated trials testing ivermectin as a COVID-19 treatment, which endangered participants:

"There were hundreds upon hundreds of low-quality, heavily biased trials started, most of which were never finished. Those that were completed carried such a high risk of bias that they should never have been used to guide practice. Not only was that science wasted, but it actually caused harm to patients. If you look at the first systematic review of ivermectin, it included all the trials, even those with a very high risk of bias or clear signs of fraud. It initially suggested that ivermectin worked against COVID-19, which led to patients receiving a drug that was both ineffective and potentially toxic." (Expert 11, Bioethicist and policy advisor)

Economic incentives

Experts observed that financial and commercial motivations, combined with strong competition and time pressure, play a major role in driving accelerated clinical trials and bring associated problems in research ethics, integrity, and justice. In particular, they discussed how economic pressures can create harmful incentives, leading to ethical issues such as increased health risks for patients, integrity issues such as publication pressure and

weak open-science practices, and justice issues such as unfair prioritization of which trials are accelerated.

Safety issues

First, accelerating trials primarily for economic gain can create ethical problems because shorter timelines often mean the product is tested in fewer people, increasing the risk that side effects are missed. In addition, two global health researchers noted that the desire to expand markets quickly can lead to promoting vaccines in children or other specific groups even when full safety data for those populations is not yet available.

Publication and open science issues

Second, experts described how the combination of competition and urgency during the COVID-19 crisis pushed research teams in the Global North to publish results as quickly as possible, sometimes resulting in lower-quality papers. Several experts also pointed out that commercial interests influenced how knowledge was shared during COVID-19 vaccine development. Although open science and open data can accelerate progress during a crisis, the private sector did not consistently share information with others. According to one global health researcher, this lack of sharing led to delays, wasted resources, and widened inequalities in countries' access to COVID-19 vaccines.

Prioritisation issues

Finally, the experts pointed out that financial motivations often lead to uneven prioritization of research topics, as these interests largely determine which trials are accelerated. This pattern can widen existing global disparities in health outcomes, research participation, and access to new scientific developments. Specialists in global health and policy noted that acceleration is typically reserved for conditions that primarily affect wealthier nations, even when clear health needs exist for illnesses that burden lower-income regions. One global health researcher and policy advisor observed that the COVID-19 pandemic illustrated this imbalance clearly, acting as a 'double-edged sword': it enabled swift development and availability of COVID-19 vaccines while slowing advancement on treatments for other diseases. The consequences for conditions such as Mpox vaccines or XDR-TB therapies were described as follows:

"In principle, every patient should matter equally. Yet when comparing tuberculosis with COVID-19, both caused around 1.5 million deaths, or 1.5 to 1.6 million in the case of tuberculosis. The real difference lies in the amount of resources allocated to each disease, which seems to depend mainly on where the affected patients live." (Expert 24, professional working at an NGO).

Overall, the experts concluded that the economic and commercial pressures pushing accelerated clinical trials tend to reinforce gaps in access to medicines and scientific knowledge, particularly when certain diseases or regions do not represent profitable opportunities in the competitive biomedical field.

Recommendation: equitable knowledge sharing and governance in science

In broad terms, the experts called for stronger international oversight of clinical trials that actively incorporates the perspectives and requirements of low- and middle-income countries (LMIC). They emphasized the importance of open knowledge exchange across borders and of closer cooperation between the public and private sectors, especially in times of crisis. One global health researcher recounted how two large pharmaceutical companies refused to share mRNA vaccine technology with South Africa's vaccine technology hub during the COVID-19 pandemic, hindering local production efforts in LMICs. Specialists from regulatory agencies also underscored the need for improved global coordination in responding to global health emergencies. An EMA expert highlighted the value of including a wider range of regions in clinical trials—beginning with robust European systems and extending to genuine global partnerships to achieve faster, more effective outcomes.

This study shows that accelerated clinical trials give rise to important and sometimes distinctive research ethics and integrity challenges. While earlier publications had already noted issues such as difficulties adapting consent procedures [22, 23, 31], unfair allocation of research resources during emergencies [18, 19], or rushed REC review processes [16], the present work captures the perspectives of a diverse group of key stakeholders and connects the identified problems to existing literature. Newly highlighted challenges include pressure surrounding informed consent and the exclusion of particular population groups; heavy demands and

insufficient guidance for fast-track ethical reviews; inadequate science communication and undefined communication responsibilities that undermine public confidence; and the combined effects of economic motivations, intense pressure, poor coordination, and limited collaboration that intensify global inequalities. The experts also suggested several approaches to mitigate these difficulties, such as greater public engagement and stronger international cooperation strategies.

Ethical concerns in accelerated clinical trials are not always immediately obvious to those involved in running the studies — including some of the experts interviewed — yet they often lie just below the surface and frequently extend beyond the usual scope of research ethics committee evaluations. Findings from Godskesen *et al*. [32] support this observation, showing that professionals in clinical trials commonly rely entirely on RECs to identify and address ethical issues. This creates an epistemic gap in the ethical awareness of researchers and other stakeholders, leading to important ethical questions receiving insufficient attention.

Although many experts considered the REC review adequate to maintain high ethical standards in accelerated trials, several limitations were reported. Ethics specialists and policy advisors described how RECs dealt with overwhelming workloads and limited guidance when conducting rapid reviews of COVID-19-related protocols, and noted that proper scientific review was frequently missing. Earlier studies had linked such shortcomings to the lack of national rules governing RECs, weak collaboration among researchers, and substandard protocol design [15, 16]. However, relatively little attention has been given to the absence of targeted training and clear instructions, or to the unclear assignment of responsibilities for scientific review in accelerated clinical trials. In Europe, the Clinical Trials Regulation divides trial assessment into two sections: Part I addresses technical and scientific aspects such as pharmaceutical quality and study methodology, while Part II covers matters relevant to the local context, including informed consent [33, 34]. Although each member state can decide who evaluates each part, ethical considerations can surface in both sections. In practice, RECs in many countries review both Parts I and II, even though the latter may be officially assigned to another body [35]. While greater REC involvement can improve ethical oversight, it also adds to the burden on committee members, who already faced shortages of guidance and expertise regarding accelerated trials during the COVID-19 pandemic.

The study indicates that insufficient global coordination, combined with competitive pressures and economic interests, can compromise the relevance and scientific strength of accelerated clinical trials. Previous work has shown that economic drivers and poor coordination often lead to scattered resources and duplicated efforts, resulting in underpowered studies that favor volume over quality [18, 20]. In global health emergencies, these problems further widen economic and health gaps, particularly for low- and middle-income countries (LMIC) [36-38]. While unequal vaccine distribution has received the most attention in the literature [39], the current findings also highlight how limited knowledge sharing between the Global North and the Global South during accelerated research contributes to growing inequalities [36].

Drawing on the conceptual lens of epistemic injustice [40, 41], we maintain that rushing clinical trials without adequate global collaboration and broad inclusion can produce unfair epistemic outcomes that harm LMICs and sidelined communities. Epistemic injustice occurs when harm is inflicted on people or groups in the activities of producing, circulating, or applying knowledge [41]. Our investigation indicates that when trials are steered chiefly by profit considerations instead of genuine population health priorities, the knowledge generated may bypass vital health concerns that matter greatly to LMIC and/or overlooked communities. Over recent decades, the market-driven style of globalization and the commercialization of pharmaceutical research have curtailed LMIC authorities' power to set their own research directions and direct high-demand projects, such as accelerated clinical trials [42]. Given that these territories usually offer little economic payoff, there are few monetary reasons to rush trials there. Consequently, LMICs face a higher risk of serving merely as locations for investigators and international drug firms from prosperous countries to gather data, rather than functioning as genuine partners who both contribute to and benefit from rapid research. On top of that, the very labeling and ranking of what qualifies as a 'global' health crisis are regularly set by bodies in wealthier regions, which steer which medical problems receive fast-tracked focus and which stay ignored. All these elements can leave LMICs carrying the burden of research involvement while gaining little in return or influencing scientific discourse [36-38], thereby sharpening the

economic and epistemic unfairnesses already present between richer and poorer parts of the world.

Fast-tracked clinical trials show a pattern of worsening difficulties that appear in every trial, for instance, ensuring that samples truly reflect target populations. Although the specialists we consulted accepted that bringing in particular at-risk individuals proves especially tough inside accelerated clinical trials, they gave little attention to the specific obstacles of enrolling people from overlooked communities such as ethnic minorities. Bringing such groups aboard demands extra time and customized outreach methods stemming from limited familiarity or confidence [43], elements that clash with the rapid pace required by accelerated studies. Even so, leaving out at-risk and overlooked groups can narrow information about potential adverse reactions [43-45] and deepen existing health disparities. Moreover, drawing these groups into poorly planned or rushed studies could inflict lasting damage on community trust in clinical research, especially among populations that already participate at low rates [43-45]. Beyond that, such patterns can injure confidence in clinical research more generally [24, 44, 46]. Confidence plays a pivotal role in clinical research: the broad acceptance of biomedical approaches and products is essential for delivering lasting outcomes [10]. One central purpose shared by research ethics and integrity is building trustworthiness — ensuring that investigators and organizations conduct themselves in ways that earn public confidence, which, in turn, supports and reinforces societal faith in clinical research [12, 47]. This goal can be achieved by upholding strong standards during trials, even under urgent conditions. The specialists we spoke with acknowledged the vital role public confidence played during the COVID-19 outbreak, echoing other writers who have highlighted the need for clear outreach and confidence to gain acceptance of new treatments [20, 21]. Yet confidence also connects to usefulness and epistemic worth: for society to keep or build faith in research, people need to sense that the resulting understanding and progress will genuinely serve their interests [10]. Amid emergencies and worldwide crises, this sensitive trust link between ordinary citizens and the scientific world grows especially fragile due to widespread alarm, rapidly spreading false information, and overall feelings of doubt [48].

Recommendations

Suggestions from the specialists center on advancing clinical trials through open communication and joint work, while making determined efforts to bring in groups that research has traditionally overlooked. This marks a significant shift in how acceleration occurs, especially during global health crises like the COVID-19 outbreak. The specialists pressed funding bodies and international oversight organizations to ensure the active participation of ordinary citizens and spokespeople from LMICs in accelerated trials. Shifting away from a model driven by industry toward one anchored in patients and local communities could address challenges in participant recruitment, sample diversity, public trust, and unbalanced decisions about research priorities. Although processes for involvement may take extra time, they remain workable and can deliver real gains for accelerated trial routes [48, 49].

To begin with, earlier writings indicate that engaging patients and study volunteers when shaping trial plans can help retain participants and improve clarity during consent procedures [50]. Next, drawing in the public and strengthening input from LMIC parties can boost confidence in clinical research [25, 26] and help reverse worsening worldwide and regional imbalances [49]. In addition, preparation and extended planning are necessary to ensure the involvement of patients, volunteers, and LMIC representatives is both realistic and productive within accelerated trial routes. In the end, developing relations built on confidence via inclusive practices could nurture epistemic democracy and diversity of outlooks, delivering major advantages to research bodies, ordinary citizens, and clinical investigators [51]. In this manner, the approach can assist in closing interpretive epistemic shortfalls in the understanding held by investigators and other clinical trial specialists [49], while also aiding in ending longstanding forms of epistemic injustice [40].

Limitations and future lines of research

Several constraints affect this study. First, although input from the Global South carries special weight when examining difficulties and possible solutions related to rushed research, every specialist interviewed came from the Global North. Second, patients and study volunteers were excluded from the sample because the project deliberately targeted professionals involved in the regulation, design, implementation, and publication of clinical trials. This decision aligns with the work's

defined focus and intended audience. Bringing patients and volunteers into such research would call for a different core question centered on their personal encounters with study participation, together with an updated discussion outline and recruitment method (individuals lacking a specialized professional background often find it hard to frame difficulties in terms of research ethics and integrity challenges, and this same difficulty can appear even among trained specialists). That kind of project would form a worthwhile topic for later investigation. Third, gathering participants through the authors' professional contacts could have added selection bias. Even though invitations went out to 192 specialists, those who chose to join might have shown greater awareness of or concern about ethical and integrity issues in clinical research, possibly inflating the level of thoughtful concern within the target group. At the same time, contributions from participants who can reflect carefully on these matters provide a useful, experience-based understanding of particular research ethics and integrity difficulties associated with accelerated clinical trials. Fourth, the interviews were kept to roughly 35 minutes to suit the specialists' packed timetables, which limited how deeply more intricate subjects — for instance, possible moral upsides of accelerated research — could be explored. Lastly, although the study yields valuable insights, it is constrained by recruitment hurdles. Despite reaching out to 192 people, only 25 accepted, and we were unable to arrange conversations with specialists from key bodies such as the European Commission or the WHO. This situation reveals the obstacles to reaching senior decision-makers and reflects the substantial work involved in building the purposive sample of 25 specialists.

Conclusion

The investigation provides useful insight into the key research ethics and integrity challenges associated with accelerated clinical trials. These difficulties extend well beyond simple ethics approval from RECs. Indeed, within the domain of clinical trials, both overall and accelerated, research ethics and integrity remain closely intertwined with epistemic, societal, and justice-related aspects. Consequently, more attention needs to be paid to societal and epistemic factors in clinical research. Absent combined, well-coordinated work, sturdy, reliable methods, and open, clear outreach, accelerated clinical trials will fail to achieve the full impact they might otherwise deliver. For that reason, ensuring that research remains relevant and that trials remain worthy of confidence during urgent periods becomes especially vital — not merely for developing badly needed treatments and vaccines, but also for advancing a system of clinical research that is fair both socially and epistemically. Reaching this point will require bringing many more interested parties into decision-making for accelerated clinical trials, including spokespeople from underserved geographic areas and those representing research volunteers.

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Ethics Statement: This study posed no risk to participants and was conducted in accordance with the principles of the Declaration of Helsinki. The study was conducted in accordance with the institutional regulations of the Vrije Universiteit Amsterdam. The self-check procedure of the Research Ethics Review Committee of the Faculty of Science of the Vrije Universiteit Amsterdam (BETHCIE) was passed and approved for this study. In this self-check, a series of questions is used to determine whether your research complies with the Code of Ethics for Research involving Human Participants of the Faculty of Science. The study complied with this code, and further review by the BETHCIE was not required. Additionally, all participants completed an online informed consent form and received written and oral information about the study.

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