Reimagining research partnerships: Equity, power and resilience

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Equity in clinical trial partnerships: a review of international research ethics guidance and guidelines

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Brief description of context

Equity and fairness in clinical trial partnerships are increasingly recognised as essential pillars of ethical global health research (1). There are reasonable grounds to support the notion that clinical trials may reinforce disparities if research partnerships in which they are conducted fail to prioritise fairness and respect for the local context (2, 3). This observation is underscored by recent guidance from the World Health Organisation (WHO), which calls for research partnerships to be sensitive and responsive to the deep-rooted historical and structural imbalances in global health research, as these tend to disproportionately disadvantage partners from low- and middle-income countries (LMICs) (1, 4). Based on this historical background, there is an increased drive towards decolonisation (5) of global health, including global clinical trial partnerships. Growing discourse among global health experts has highlighted the need to reframe partnerships with equity and fairness at the forefront (6-9) due to past historical injustices and practices. Historically, clinical trials conducted in LMICs have too often centred the interests of institutions and funders from high-income countries (HICs), leaving LMIC partners with limited input in study design, data interpretation, and publication (9, 10). Such practices can restrict the ability of LMIC researchers to contribute meaningfully and sustainably to local health improvements. By embracing the true meaning of partnership, which may involve rethinking certain interactions and engagements as collaborative efforts, global health research can progress towards ethical and socially responsible practices that benefit all parties involved.

Despite concerted efforts to reframe partnerships through an equity and fairness lens, there is limited scholarly research examining the relationship between the research ethics guidelines and guidance documents and actual practice. Drawing on the WHO's Guidance for Best Practices in Clinical Trials (1), we conducted a content analysis of nine well-known international research ethics guidelines and guidance documents (11-19) (see Table 1) to explore the extent to which equity and fairness were integrated into the selected guidelines, particularly within clinical trial partnerships.

Table 1: List of reviewed guidelines and guidance documents

Publisher	Title
CIOMS	International Ethical Guidelines on Health-related Research Involving Humans(11)
CIOMS	Clinical Research in Resource-limited Settings(12)
CIOMS	International guidelines on good governance practice for research institutions (13)
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use ICH Harmonised Guideline: General Considerations for Clinical Studies E8(R1)(14)
ICH	International Conference On Harmonisation of Technical Requirements For Registration of Pharmaceuticals for Human use ICH

	Harmonised Tripartite Guideline: Pharmaceutical Development Q8(R2)(15)
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ICH Harmonised Guideline: General Principles for Planning and Design of Multi-regional Clinical Trials E17(16)
WMA	Declaration of Helsinki(17)
WMA	Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks(18)
Good Clinical Trials Collaborative	Guidance for Good Randomized Clinical Trials(19)

We purposefully selected foundational documents key to international clinical trial ethics, which are also products of global consensus processes, with an understanding that there is a reasonable expectation that parties involved in clinical trial partnerships will likely conform to them. Data extraction encompassed keyword searches and contextual analysis of selected words related to equity and fairness to establish relevance. This paper presents and discusses the coverage of domains related to partnership equity, based on a content analysis of the documents, and recommends concrete actions to enhance clinical trial partnership practices and accountability.

Summary of key findings from the study

None of the nine reviewed documents was explicitly developed to guide clinical trial partnerships. Unsurprisingly, there is no definition or universal framework of what constitutes an equitable clinical trial partnership across the reviewed documents. However, in one way or another, most of the documents refer to responsibilities that research players (researchers, research institutions, and communities) need to meet for efforts to advance fair partnership practices to be realised. The geographic representation of members involved in the development of the guidelines differed, with a majority showing a disproportionate representation of high-income countries compared to LMICs. For example, 4 out of 32 (about 12%) members of the working group for the Clinical Research in Resource-Limited Settings guideline were from the African continent. Furthermore, only 5% (3 out of 57) of individuals who provided commentary on the Working Group report on the Revision of the 2002 International Guidelines for Biomedical Research Involving Humans were from Africa.

We identified five themes related to equity in clinical trial partnerships, namely (i) Ethical foundations; (ii) Contextual and structural determinants; (iii) Partnership activities, procedures and dynamics; (iv) Management and oversight, and (v) Sustainability. In terms of overall representation of themes across the reviewed literature, the two Council for International Organizations of Medical Sciences guidelines (i) International Ethical Guidelines on Health-related Research Involving Humans and (ii) Clinical Research in Resource-Limited Settings contained the largest amount of content related to equity in clinical trial partnerships. The documents with the least content related to equity in clinical trial partnerships were the ICH: Pharmaceutical Development (Q8(R2) and the ICH Harmonized Guideline: General Considerations for Clinical Studies E8(R1).

Examining the representation of content from the nine reviewed documents according to the five themes, most documents recognised that equitable partnerships should be grounded in ethical principles, which serve as the moral compass for all research partnerships, including justice, respect, fairness, transparency, and reciprocity. Another common thread in the documents was the recognition that effective and ethically sound partnerships can only be achieved after a deep and comprehensive understanding of contextual factors. Some of the guidelines proactively warn against "ethics dumping" (12), conducting research in LMICs that is considered unethical in HICs. For example, the Clinical Research in Resource-Limited Settings guideline states that *"Sponsors of research or investigators cannot, in general, be held accountable for unjust conditions prevailing where the research is conducted, but they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities."* (12). In relation to partnership activities,

procedures, and dynamics, the emphasis in most documents is on proactive engagement, collaborative design, planning, transparency, and the establishment of formal agreements, as well as the equitable distribution of duties and tasks. Some of the reviewed documents also recognise effective research management and oversight as critical components for upholding equity. Lastly, sustainability was viewed as an integral component of any equitable research partnership.

Across the nine documents, the most common theme addressed was partnership activities, procedures and dynamics. This theme was addressed in all reviewed documents. Comparatively, contextual and structural determinants were the least addressed theme in all the reviewed documents. A close examination of the content in the documents reveals efforts and guidance in some of the documents to transition from superficial research partnerships to more equitable ones. Examples of such documents include the International Ethical Guidelines on Health-related Research Involving Humans (11), Clinical Research in Resource-limited Settings (12) and the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants (17).

Discussion of ethical issues

This section discusses the conceptual and practical gaps which hinder efforts to achieve equitable clinical trial partnerships, as identified in nine reviewed documents, many of which emerge from global consensus processes. Broadly, these can be classified as definition gaps, geographic representation, context-specificity and power dynamics. We discuss these in turn.

There is no universally accepted definition of an equitable clinical trial partnership across the reviewed research ethics guidelines and guidance documents. The lack of a universal definition of an equitable clinical trial partnership renders partnership equity an ideal that lacks practical implementation mechanisms and enforceability. You can't implement what you can't define, nor can you measure, operationalise and enforce its implementation. Multiple definitions in the research ethics literature highlight key dimensions of equitable research partnerships, delineating the principles and practices that underpin partnership equity in global health research (10, 20). For example, these include mutual respect, shared decision-making, and balanced benefits among partners throughout the research process. However, the precise contours of clinical trial partnership equity remain ambiguous. The ambiguity arises from both the different documents and the application of the principles. Questions also arise regarding how the principles of equity can be translated into practice, including metrics for the different elements of an equitable partnership, the threshold for equity, and whose responsibility it is to translate and enforce these principles.

Findings from the review reveal a lack of parity in the geographical representation of countries that contributed to the development of some of the guidelines, as well as a lack of transparency regarding the criteria used to select the countries represented in the guidelines' development. Concerns have been raised that the frameworks and guidelines reflect the voices of researchers and institutions from HICs, leaving the perspectives of LMICs underrepresented. It is further argued that the definitions exclude the contributions of individuals and communities directly affected by the research, resulting in a gap between the stated goals of equity and the intended impact on the host communities. Similar observations were made in a review of partnership equity toolkits, which revealed that twenty-three countries were involved in the development of the toolkits, with less than half of the toolkits developed with representation from LMICs (21). However, whether representation achieves the intended goal of equitable clinical trial partnerships or whether specific quotas should be observed for representation remains a subject for debate. In our opinion, it's not a question of numbers and parity but rather the processes followed in identifying individuals capable of representing the interests of specific populations. Furthermore, although equitable partnerships are formulated and presented as universal in the literature, the requirements for equity can be, to a large extent, context-specific. A one-size-fits-all conceptualisation may, therefore, fall short of addressing the unique needs of partners from diverse research contexts.

Another critical dimension related to the conceptualisation of equity is that it is not a static concept - different players and partners define it to serve their interests (22, 23). The definition and subsequent negotiation of meanings of an equitable partnership or collaboration could, therefore,

be viewed as a political battle where the most influential perspectives dominate partnership structures, often marginalising the other partners' needs and perspectives (24). Because different partners may potentially strive to exert power and influence over what constitutes equitable partnerships to preserve and promote their interests, the evolution of the concept in response to power dynamics may be inevitable. This dynamic may influence the choice of equity toolkits that partners select to assess or benchmark their partnership practices, giving them the flexibility to choose what serves their best interests, regardless of conformity to true equity ideals.

From an epistemological perspective, questions arise regarding whose knowledge and experience inform the ethical deliberation and frameworks applied to clinical trials. Are the views from the global south represented, and if so, with what outcome (25, 26)? These considerations are critical, considering the inherent asymmetric power dynamics between HIC institutions, which primarily fund global clinical trials, and LMIC institutions, which have traditionally been the recipients of research funding. How then does this impact the implementation of fair practices in clinical trials, and what are the practical consequences? Clinical trials are resource-intensive and require substantial financial investments. As the adage goes, he who pays the piper calls the tune. The partner with financial muscles, typically from HICs, is more likely to dictate the research agenda and dominate the research partnership, which compromises the ideals of equity. Are there ways to even out the research funding landscape or adjust the value of contributions and resources from partners? How are the different contributions from partners weighted in the broader research partnership relationship?

Conclusions and recommendations

Our study identified gaps in nine purposefully selected foundational documents central to clinical trial ethics and international health research governance, commonly referenced during the planning and implementation of clinical trials. These gaps included the absence of a universally agreed-upon definition or standards for fair clinical trial partnerships, a lack of parity in the geographic representation of contributors to resources on clinical trial partnership equity, context specificity, power imbalances between researchers and institutions from different settings, as well as challenges in enforcing equity guidelines and toolkits.

The absence of universally accepted standards for fair partnerships makes it challenging to establish and implement universally applicable and acceptable tools and guidelines for clinical trial partnerships. Although equity principles are widely available in the bioethics literature, it is essential to translate them into practical applications. This process requires ongoing effort and commitment from all stakeholders. The process could benefit from a review of the literature, like the one we conducted. Additional empirical evidence, gathering the perspectives of clinical trialists, funders, and communities on what constitutes a truly equitable clinical trial partnership, could complement these efforts. Rather than developing new guidelines, it may be worthwhile to revise an existing document to ensure that it adequately addresses best practices for equitable clinical trial partnerships. The WHO can facilitate this process.

Mechanisms for addressing geographic representation, context-specificity and power imbalances between researchers and institutions from different settings should be developed. The specific form and content of such mechanisms and metrics require both empirical and conceptual evidence, with input from clinical trialists, research regulators, and ethicists from across the geographic divide. A good starting point could be convening a meeting of key stakeholders to discuss these issues and reach a consensus.

Enforcement mechanisms to ensure equitable partnership practices are critical. One recommendation is to establish independent oversight committees charged with developing and implementing strategies to evaluate clinical trial partnership practices, ensuring that, at a minimum, partners fulfil the key elements or benchmarks of partnership equity. The benchmarks could be developed from the main themes identified in this study. They could also develop models, guidelines, toolkits, and checklists to assess the formation of partnerships and monitor the implementation of partnership equity. The committees could also serve as arbiters for dispute resolution.

In conclusion, our study suggests areas where existing guidance can benefit from further development and refinement. Explicit and robust integration of equity principles within core clinical trial guidelines and benchmarking frameworks should be prioritised to foster ethical and collaborative clinical trial partnerships. Input from clinical trialists is crucial to developing the most effective policies and guidance for equitable partnerships and their implementation. Empirical studies on what aspects of research partnerships are still colonial mechanisms, an understanding of the perspectives of different stakeholders on what they consider equitable partnerships, and appropriate metrics for equitable partnerships should be prioritised. Fostering equitable partnerships can pave the way for clinical trials that not only advance scientific knowledge but also reflect a genuine commitment to social justice and mutual respect. While equity and fairness have been valuable guiding concepts in the research partnership discourse, it may be necessary to reimagine alternative frameworks for deeper insights.

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