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Article abstract

This letter proposes extending the post-trial provisions of the updated Declaration of Helsinki beyond pharmaceutical drugs to include AI tools, particularly those developed using data from low- and middle-income countries. Such an extension would help prevent data colonialism and ensure more equitable access to these tools, fostering fairness in global health research.

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LETTRE À L'ÉDITEUR / LETTER TO THE EDITOR

Trial-centrism in the Declaration of Helsinki: A Challenge for Post-Study Access and Preventing Data Colonialism in AI-Driven Health Research

Hazar Haidar[a], Ehsan Shamsi Gooshki[b,c]

Résumé
Cette lettre propose d'étendre les dispositions post-essais de la Déclaration d'Helsinki actualisée au-delà des médicaments pharmaceutiques pour inclure les outils d'intelligence artificielle, en particulier ceux qui sont développés à partir de données provenant de pays à revenu faible ou intermédiaire. Une telle extension contribuerait à prévenir le colonialisme des données et à garantir un accès plus équitable à ces outils, favorisant ainsi l'équité dans la recherche en santé mondiale.

Mots-clés
Déclaration d'Helsinki, accès post-étude, colonialisme des données, IA, recherche en santé

Abstract
This letter proposes extending the post-trial provisions of the updated Declaration of Helsinki beyond pharmaceutical drugs to include AI tools, particularly those developed using data from low- and middle-income countries. Such an extension would help prevent data colonialism and ensure more equitable access to these tools, fostering fairness in global health research.

Keywords
Declaration of Helsinki, post-study access, data colonialism, AI, health research

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The recent update to the Declaration of Helsinki (DoH), despite presenting some important steps forward such as adopting environmental sustainability as a new principle (1), still suffers from a significant limitation: its clinical trial centred-approach. Unlike other positive changes, such as expanding the mandate to protect individual participants beyond the scope of their relations with physician-researchers, this trial-centrism is both self-restrictive and counterproductive. The trial-centrism is particularly manifest in Articles 22 and 34, which address requirements for post-trial provisions, and present an approach that lacks a broad view of medical research where post-research access to resulting products extends beyond pharmaceutical drugs. It should, we argue, also include studies aimed at developing non-conventional medical tools, such as those based on artificial intelligence (AI) (2). In this letter, we propose extending post-trial access to include medical tools and software that are increasingly used as a part of standard care, especially when these tools are developed using data from low- and middle-income countries (LMICs). This aligns with accepted ethical standards in medical research to ensure that populations in these countries benefit fairly from the use of their data, while maintaining trust in the research process.

Growing concerns are emerging about data colonialism (3), a practice where data from LMIC are extracted and controlled by powerful entities (e.g., the biopharmaceutical industry), often without fair compensation or benefit to the source communities. This practice establishes new "data relations" (3) that mirror the extractivist aspects of historical colonial dynamics. Such data exploitation risks deepening global inequalities while further entrenching marginalization of the communities providing clinical research data (4). Further, this dynamic not only reinforces power imbalances, it also widens the technological and economic gaps between the Global South and the Global North, leaving marginalized communities further behind as AI advances. This trial-centrism is reinforced by implicit colonial language, such as the phrase "sponsoring and host countries" in Article 23. This dichotomic phrasing overlooks more neutral alternatives such as "all involved countries". Additionally, an individualistic focus on health data that emphasizes identifiable and re-identifiable data neglects the importance of permanently anonymized data from specific communities. Together, these factors increase ethical concerns in medical research using big data, particularly for developing medical AI tools.

Extending post-trial provisions to include AI tools would ensure that communities who contribute data, especially those in LMIC, are not left without access to the technologies and tools that emerge from their contribution to research. It would also establish a framework aiming to prevent the exploitation of these communities while providing them with the right to access the benefits of innovations. This expansion might also serve as a safeguard against data colonialism, promoting a more equitable distribution of AI's potential benefits across global communities.

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