

Peer Review

Review of: "Trust and Trade: Ethical Reflections on Patient Trust and the Monetisation of Real-World Data"

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This commentary provides a timely and conceptually sophisticated exploration of ethical governance challenges surrounding the monetisation of real-world data (RWD) and its implications for patient trust. The manuscript's primary strength lies in its integration of regulatory science, health policy, and ethical theory, particularly through the application of relational ethics and the social responsibility of science to real-world evidence (RWE) governance. The discussion is well supported by contemporary regulatory frameworks, case studies, and patient perception literature, which enhances both relevance and credibility. The five proposed safeguards are clearly articulated, pragmatic, and grounded in existing policy infrastructure, offering meaningful contributions to ongoing debates regarding transparency, reciprocity, and legitimacy in secondary data use. Additionally, the balanced acknowledgement of counterarguments—such as the ethical risks of data non-use—strengthens the manuscript's intellectual rigor and neutrality. However, several areas could be further strengthened. As a normative commentary, the manuscript would benefit from a clearer methodological description regarding how patient surveys and governance case examples were selected and synthesised. Some sections contain conceptual repetition and could be streamlined to improve clarity and readability. Furthermore, while the safeguards are persuasive, the discussion could be enhanced by incorporating more empirical evidence demonstrating their feasibility, cost implications, and measurable impact on trust outcomes across diverse healthcare systems, particularly outside European and UK regulatory contexts. The manuscript would also benefit from a more detailed exploration of potential unintended consequences, such as administrative burden or stakeholder resistance. Overall, this commentary represents a thoughtful and policy-relevant contribution to the evolving discourse on ethical stewardship of health data, and with

minor structural refinement and expanded empirical contextualisation, it would further strengthen its scholarly and practical impact.

Declarations

Potential competing interests: No potential competing interests to declare.