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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 addresses a critical blind spot in the current pharmaceutical regulatory landscape. As the FDA and EMA increasingly rely on Real-World Evidence (RWE) for regulatory decision-making—spanning from initial market authorization to post-market safety surveillance—the governance frameworks have largely focused on methodological rigor and data integrity (e.g., ALCOA+ principles). The author correctly identifies that while we have robust standards for how data is analyzed (STaRT-RWE, HARPER), we lack a cohesive framework for the relational ethics of its secondary use.

From a regulatory affairs perspective, the author's proposal for "mandatory registration of non-interventional studies" is particularly compelling. Just as ClinicalTrials.gov registration became a standard for interventional trials to prevent selective reporting, extending this requirement to RWE studies would significantly enhance transparency and align with the principles of Good Clinical Practice (GCP).

I also support the author's critique of the current "passive consent" models. In the context of the European Health Data Space (EHDS) and the FDA's evolving RWE guidance, the distinction between "legal compliance" and "social legitimacy" is becoming a business-critical risk for pharmaceutical developers.

However, regarding the proposed "benefit-sharing" safeguard: while ethically sound, practical implementation would require careful alignment with existing anti-kickback statutes and fair market value assessments to ensure it is not bolstered by commercial incentives.

Overall, this is a timely and necessary contribution that moves the conversation beyond technical validation and into the essential realm of public trust, which is the foundation of the regulatory social contract.

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Declarations

Potential competing interests: No potential competing interests to declare.