

Peer Review

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

Dr. Raghavendra Kumar Gunda^{1,2}

1. Pharmaceuticals, Vignan's Foundation for Science, Technology & Research, Guntur, India; 2. School of Pharmaceutical Sciences, Vels Institute of Science, Technology & Advanced Studies (VISTAS), Chennai, India

This manuscript presents a **timely, well-argued, and conceptually robust normative commentary** addressing patient perceptions of fairness, reciprocity, and legitimacy in the secondary use and monetisation of real-world health data (RWD). The author convincingly argues that current regulatory and HTA frameworks, while methodologically mature, insufficiently address ethical stewardship and relational trust from a patient perspective.

The paper is **clearly positioned as a policy and ethics commentary rather than empirical research**, and it appropriately synthesises regulatory frameworks, governance case studies, and patient-attitude literature. The integration of **relational ethics** and the **social responsibility of science** provides a strong theoretical foundation. The proposed **five pragmatic safeguards** are concrete, feasible, and highly relevant to current debates surrounding the European Health Data Space (EHDS).

Overall, the manuscript makes a **substantive and original contribution** to discussions on RWE governance, transparency, and legitimacy

Strengths

Timeliness and Relevance

Addresses a critical and under-examined dimension of RWE governance: patient perceptions of fairness and reciprocity in data monetisation.

Highly relevant given the implementation of the EHDS and the growing role of commercial actors in data ecosystems.

Clear Scope and Positioning

The manuscript clearly delineates its focus as a normative commentary, avoiding inappropriate claims of empirical novelty.

The boundaries of analysis (ethical legitimacy rather than methodological rigour) are well defined.

Strong Conceptual Framework

Effective use of relational ethics and social responsibility of science to frame legitimacy beyond legal compliance.

The discussion moves coherently from theory to governance implications.

Pragmatic Policy Contribution

The five safeguards (transparent consent, disclosure of monetisation, patient governance, benefit-sharing, protocol registration) are actionable and grounded in existing international practices.

These safeguards meaningfully extend the concept of “evidence integrity”.

Balanced and Nuanced Argumentation

Acknowledges the ethical risks of both data misuse and data non-use.

Recognises legitimate industry and regulatory needs while maintaining a patient-centred ethical stance.

Major Comments

Clarification of Normative Authority

While the manuscript persuasively argues for expanded ethical stewardship, it would benefit from a brief clarification of:

Whether the proposed safeguards are intended as *ethical expectations*, *policy recommendations*, or *future regulatory standards*.

Explicitly articulating this would strengthen interpretability for policymakers and regulators.

Operationalisation within EHDS

The EHDS is referenced as a pivotal opportunity. Consider:

Adding a short subsection explicitly mapping the five safeguards onto EHDS governance structures (e.g., health data access bodies, pricing models, secondary-use permits).

This would further enhance policy applicability.

Global Generalisability

The manuscript draws heavily on UK and EU examples, which are appropriate but may limit perceived global transferability.

A brief acknowledgement of how these arguments may translate (or not) to low- and middle-income country (LMIC) contexts or non-universal health systems would strengthen the international appeal.

Minor Comments

Terminology Consistency

The terms *commercialisation* and *monetisation* are well defined but occasionally used interchangeably. A short reminder sentence early in the discussion could aid clarity.

Streamlining Length

While comprehensive, some later discussion sections (particularly those reiterating trust erosion and legitimacy) could be modestly condensed without loss of substance.

Stylistic Refinements

The rhetorical phrase “That is MY DATA” is effective but could be signposted more explicitly as a narrative device rather than a normative claim, especially for more formal policy audiences.

Protocol Registration Safeguard

The fifth safeguard could benefit from one concise sentence distinguishing *registration for transparency* from *regulatory approval*, to avoid misinterpretation.

Declarations

Potential competing interests: No potential competing interests to declare.