Commentary

Trust and Trade: Patient Perspectives on the Ethics of Real-World Data Monetisation

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Real-world data (RWD) and real-world evidence (RWE) are now central to healthcare decision-making, supporting regulatory submissions, health technology assessments (HTA), and scientific communication. Yet patients whose data fuel these processes rarely see transparency or benefit when their information is commercialised. Governance frameworks from the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and other bodies emphasise methodological rigour and transparency, but they seldom address fairness, reciprocity, or perceptions of legitimacy from a patient perspective.

This commentary argues that evidence integrity must extend beyond technical standards to encompass ethical stewardship. Drawing on case examples from the UK, EU, and North America, I show how opacity in consent processes, selective disclosure of data use, and absence of benefit-sharing widen the trust gap. Patients contribute information under the assumption it will improve care, not simply generate commercial value or institutional advantage.

To address this, I propose five pragmatic safeguards: (i) transparent, plain-language consent; (ii) mandatory disclosure of monetisation models; (iii) governance boards with patient representation; (iv) reinvestment of commercial gains into patient support, public health, and digital tools; and (v) mandatory registration of non-interventional studies in public registries. Together, these measures extend evidence integrity to include fairness, reciprocity, and legitimacy. The future of RWE depends not only on scientific validity but also on whether patients trust that their data are handled responsibly and ethically. Perhaps it is time to move beyond passive consent and towards a new call for accountability—captured in a simple but powerful reminder: *"That is MY DATA."*

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Introduction

Real-world data (RWD) are firmly embedded in regulatory science and health policy, with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) formally recognising real-world evidence (RWE) as a key element across the product lifecycle [1][2]. The Data Analysis and Real World Interrogation Network in the European Union (DARWIN EU) exemplifies the move from principles to execution by routinely generating regulator-led studies across Europe [3]. Yet these frameworks prioritise methodological adequacy and transparency; they do not meaningfully adjudicate the fairness of monetised secondary use from a patient's point of view.

Concurrently, the European Health Data Space (EHDS) introduces a legal infrastructure for the primary and secondary use of electronic health data (in force from 26 March 2025), explicitly enabling reuse for research and policy while strengthening individual control [4]. This represents a pivotal opportunity to align governance with public expectations around trust and benefit-sharing.

This paper does not attempt to re-evaluate the methodological standards already established for RWE. Instead, it asks a more fundamental set of questions:

- How do current regulatory and health technology assessment (HTA) frameworks address—or fail to address—the fairness of secondary use and monetisation of RWD?
- To what extent are patients informed about, and comfortable with, their data being transformed into economic value for institutions, companies, or individual careers?
- What safeguards could strengthen trust, reciprocity, and legitimacy in the secondary use of health data?

The objective is to extend the concept of evidence integrity beyond methodological rigour, arguing that patients' trust and perceptions of fairness must be central to the future credibility of RWE.

What current frameworks cover—and what they miss

Regulatory and HTA-adjacent guidance has matured rapidly: STaRT-RWE standardises protocol transparency [5]; HARPER provides a harmonised protocol template [6]; and the EUnetHTA REQueST tool articulates registry quality criteria [7]. These instruments sharpen scientific validity and reporting, but they are agnostic about who benefits economically from secondary use and how that is disclosed to patients.

The FDA's RWE framework and its 2025 programme updates reiterate definitions and decision contexts for using RWD in approvals and labelling changes—again, squarely methodological. The result is a governance landscape that improves science but leaves the ethics of monetisation and reciprocity largely to institutional policies and contracts [2].

The patient trust gap

Survey work in the United Kingdom (UK) consistently shows high trust in the National Health Service (NHS) as a steward of data, but markedly lower trust in pharmaceutical and technology companies. In 2024, NHS Digital reported 72–83% trust in the NHS to keep data secure; curated evidence reviews from Understanding Patient Data (2021–2024) similarly document both broad support for data use and persistent unfamiliarity with secondary uses. Public preference skews towards de-identified data and transparency about purpose [8].

Historic studies [9] and recent syntheses show sustained public discomfort with commercial access—especially for marketing or insurance purposes. A 2024 systematic review also highlights that willingness to share for third-party uses hinges on trust, perceived public benefit, and clear safeguards [9].

Global consumer research echoes this. Deloitte's 2024–2025 surveys find rising scepticism toward generative AI in health contexts, driven by distrust in outputs and unease about data handling—signals that any monetised data ecosystem must take seriously [10].

Case illustrations: when opacity erodes legitimacy

DeepMind–Royal Free (UK): In 2017, the UK Information Commissioner's Office concluded that the Royal Free NHS Foundation Trust failed to comply with data protection law in sharing 1.6 million patient records with Google's DeepMind to develop and test the Streams app, citing inadequate patient information. The episode is now a canonical example of "legal-process first, engagement later" and its reputational cost [11].

NHS national data platform and pricing debates: In parallel with NHS England's Federated Data Platform build-out, policy discussions have explored a national health data service and pricing structures to recover costs of access. Editorials warn that perceived private profit from NHS data could undermine trust without visible public benefit and transparency [12].

Both cases illustrate what happens when public data are treated primarily as assets rather than as contributions from individuals—people who may rightfully feel, 'this is my data,' yet are rarely consulted on its use.

Monetisation: ethics and economics

Health systems, electronic health record (EHR) vendors, and third-party platforms increasingly treat de-identified data as an asset class. Recent scholarship documents data collection and commercialisation practices in primary care record industries, and ethics papers debate whether and when for-profit secondary use of publicly generated data is acceptable. Publics tend to support research-oriented reuse with clear public benefit but react negatively to opaque commercial models [13].

In the UK, British Medical Journal (BMJ) commentary has cautioned against "selling NHS patient data" without clear benefit-sharing and transparent governance—again reflecting a legitimacy rather than a pure privacy concern [14]. The National Data Guardian's 2023–24 report similarly centres "demonstrably trustworthy" use as essential to public confidence [15].

From method to meaning: expanding "evidence integrity"

Scientific transparency tools (STaRT-RWE, HARPER, REQueST) should be complemented by trust-building practices that speak to meaning for contributors: who profits, who governs, and who benefits. Absent this, even lawful, de-identified reuse may fail the legitimacy test—especially at scale or when private actors are central [16]. Further discussion of secondary use under the European Health Data Space (EHDS) and privacy-enhancing technologies is provided by van Drumpt et al. [17].

Five pragmatic safeguards

1. **Plain-language, layered consent (or notification) for secondary uses.** Consent materials should explain what kinds of secondary use and monetisation exist, by whom, and with what controls, aligned to EHDS guardrails and national opt-out regimes [4].
2. **Mandatory disclosure of monetisation models.** Public registries of data access agreements (who accessed, for what, value exchanged) would normalise transparency and enable audit—akin to trial registration for methods [18].

3. **Governance with patient representation.** Data access boards for secondary use should include trained patient/public members with real voting rights. This is consistent with the National Data Guardian's emphasis on "demonstrably trustworthy" use [15].
4. **Visible benefit-sharing.** Where commercial value is created from public data, a defined proportion should be reinvested into patient support, patient associations, public health, digital tools, or the data infrastructure itself. Ongoing UK work on pricing/cost-recovery shows how models can be designed to avoid perceptions of "selling" while still covering costs [12].
5. **Protocol registration and transparency.** All non-interventional studies using patient data—whether for HTA, regulatory submissions, or scientific communication—should be registered in publicly accessible databases such as the EU PAS Register, ClinicalTrials.gov, or ENCePP [19][20][21]. Registration of objectives, endpoints, and analysis plans creates a transparent record that reduces selective reporting, clarifies intent, and enhances accountability. This expectation should extend to both submission-grade and non-submission RWE, ensuring that the use of patient data is always visible and auditable [22][23].

These steps do not supplant methodological standards; they extend evidence integrity to include fairness, reciprocity, and legitimacy.

Legitimate secondary uses

Access by industry to patient-level data for purposes such as HTA submissions, regulatory evidence generation, and peer-reviewed scientific communication should be regarded as legitimate and essential. These activities contribute to transparency in decision-making, accelerate patient access to innovative therapies, and improve clinical practice.

However, legitimacy requires that such uses are conducted within the same framework of safeguards: plain-language consent, disclosure of access agreements, patient-inclusive governance, visible benefit-sharing, and mandatory registration of protocols in publicly accessible registries such as the EU PAS Register, ClinicalTrials.gov, or ENCePP. Without these guardrails, even necessary evidence generation risks being perceived as exploitation rather than collaboration.

Discussion

The analysis presented here highlights a structural blind spot in the governance of RWE. Regulatory and HTA frameworks have succeeded in advancing methodological rigour, transparency, and data quality, but they remain silent on fairness, reciprocity, and benefit-sharing. Surveys and case studies show that while patients broadly support data use for public benefit, they are consistently uneasy about opaque commercial access and monetisation. This trust gap poses a risk not only to the legitimacy of individual initiatives but to the credibility of RWE as a scientific field.

The safeguards proposed—transparent consent, disclosure of monetisation, patient representation in governance, visible benefit-sharing, and mandatory protocol registration—are not aspirational ideals but practical steps already mirrored in related domains, from trial registration to public involvement in research ethics. Embedding these five safeguards into RWE practice would extend the concept of evidence integrity from methodological adequacy to social legitimacy.

Conclusion

RWE cannot thrive on methodological excellence alone. Patients' willingness to share—and society's mandate to use—rests on trust that secondary uses (including monetised ones) are transparent, fairly governed, and deliver visible public benefit. With EHDS now in force and global transparency tools maturing, the moment is ripe to embed reciprocity into the RWE ecosystem.

The five safeguards outlined in this commentary—plain-language consent, disclosure of monetisation models, governance with patient representation, visible benefit-sharing, and mandatory protocol registration—provide a feasible framework to achieve this. Perhaps it is time to move beyond passive consent and towards a new call for accountability—one that could be captured in a simple but powerful reminder: "That is MY DATA."

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