RegenMed


# ARTICLE

## WHEN ALGORITHMS HARM

*Redefining liability when autonomous systems make or influence medical decisions.*

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## THE NEW FRONTIER OF HARM

For the first time in medical history, treatment decisions are being influenced by systems that cannot explain themselves. When a radiology model misses a tumor, or an AI triage system misroutes a patient, the harm is tangible — but the agent is intangible.

Traditional malpractice law presumes a human actor: an identifiable decision-maker who owed a duty of care. AI collapses that simplicity. The model "decides," the clinician "oversees," and the institution "implements" — but when failure occurs, accountability dissolves in the blur between them.

We now face a moral vacuum where impact exceeds responsibility.

## THE ANATOMY OF ALGORITHMIC CAUSATION

In legal terms, harm requires three elements: **duty**, **breach**, and **causation**.
AI complicates all three.

- **Duty**: Who holds the duty — the developer, deployer, or user?
- **Breach**: What constitutes negligence — bad data, poor validation, or reckless reliance?
- **Causation**: How can harm be proven when model logic is opaque and outcomes are probabilistic?

These questions are unanswerable within legacy frameworks designed for human intent. We must expand the concept of liability from *personal fault* to *procedural accountability*.

## FROM NEGLIGENCE TO PROVENANCE

In an automated ecosystem, the relevant moral object is not intent but **process**. Circle Datasets replace "who knew" with "what was logged."

Every decision — data input, model training, output interpretation — carries a verifiable timestamp and custodial signature.

This turns the legal problem of negligence into a technical question of provenance. If a model erred because its data was incomplete, that fact is demonstrable. If a clinician overrode warnings or failed to follow protocol, that, too, is visible.

Accountability becomes a property of the record, not a matter of recollection.

## SHARED BUT STRUCTURED RESPONSIBILITY

Federated architecture distributes both data and duty. Each actor — data custodian, model developer, deployment site — bears **bounded accountability**:

- The **custodian** must ensure local data accuracy and ethical compliance.
- The **developer** must document validation, limitations, and intended use.
- The **clinician** must exercise judgment within declared boundaries.

Circle Datasets harmonize these duties by embedding them in executable policy logic. Responsibility no longer depends on trust; it is enforced by code.

## THE REGULATORY CONVERGENCE

The world's major frameworks are moving in this direction. The EU *AI Liability Directive, the U.S. Good Machine Learning Practice, and the UK Medicines and Medical Devices Act* all center on transparency, traceability, and lifecycle documentation. Circle Datasets operationalize these requirements by design. Their immutable audit trails make it possible to satisfy regulators not through affidavits but through evidence. The system itself becomes the witness.

## THE MORAL MEANING OF ACCOUNTABILITY

Accountability is not only about assigning blame; it is about protecting dignity.
When a patient is harmed, what matters most is not punishment but **recognition** —
a transparent acknowledgment of cause and consequence.

Opaque systems deny that recognition. They turn suffering into mystery.
Federated provenance restores visibility, allowing medicine to face its errors honestly and repair trust.

Accountability is not cruelty; it is compassion armed with structure.

## THE PRACTICAL DIVIDEND

Structured accountability produces both justice and safety. When failures are traceable, they become teachable. When liability is clear, risk is manageable. Insurers can price coverage rationally, regulators can certify systems confidently, and clinicians can rely on tools without existential fear. The ecosystem matures from experimental to dependable. Federation turns chaos into chain of custody, and chain of custody into continuity of care.

## THE MORAL OUTCOME

The age of algorithmic medicine demands a new Hippocratic principle: First, be traceable.
In systems where no one can be held to account, everyone is unsafe. But in systems where every action carries a signature, harm can be confronted, corrected, and prevented.
Circle Datasets do not make AI infallible; they make it answerable. And in medicine, answerability is the essence of care.

## SELECTED REFERENCES


- RegenMed (2025). *Circle Datasets: The Foundation For Circle Health Coins.*
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- OECD (2024). *Accountability and Transparency in AI-Enabled Health Systems*.


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