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Reality vs. Theory: Final Roadmap Reveals Procedural Routes as the True Barrier to HealthTech Adoption

THESSALONIKI — EVOLVE2CARE has published its final evidence-validated roadmap (D1.4), correcting initial project assumptions with observed reality. The headline finding is a significant shift: the primary burden on innovators is not *substantive* regulatory requirements, but rather *procedural opaqueness*—the length and opacity of the route to approval.

Furthermore, the report highlights a critical gap in European oversight. Both innovators and review bodies are currently unprepared for the complexities of Artificial Intelligence, specifically the “reuse of collected data for model training.”

Policy Recommendations for Regulators

- **Harmonize Approval Routes:** Focus on reducing the length and opacity of the route to approval, not just the requirements themselves.
- **AI Specialization:** Establish specialized guidance for review bodies regarding AI data reuse and model training ethics.
- **Resource Recruitment:** Treat end-user recruitment as a core funded service to overcome the binding operational constraint of participant access.

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About EVOLVE2CARE

EVOLVE2CARE is a Coordination and Support Action (CSA) dedicated to strengthening HealthTech experimentation in transitional care. The consortium brings together five leading organisations: Aristotle University of Thessaloniki (AUTH), the European Network of Living Labs (ENoLL), Sploro, Anthology Ventures, and VILABS.

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