Bio-curity2.0

Trustworthy Data Enrichment for Safe & Certified Devices

XECS CALL 5 / EUREKA PROJECT

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Challenges & Objectives

R&D FUNDING

UNMET NEED

Digital Health Solutions face slow, resource-intensive certification processes. There is limited secondary use of health data and under-used real-world data (RWD), which disproportionately impacts SMEs trying to enter the market.

MARKET NEED

SMEs and MedTech innovators urgently require scalable, transparent tools to leverage data for certification while strictly maintaining safety, efficacy, and patient trust.

STRATEGIC VISION

EnrichTrust enables privacy-preserving, ethical, and verifiable data enrichment across organisations to accelerate MDR/CE/FDA certification.

The project acts as a practical frontrunner within the European Health Data Space (EHDS), demonstrating trusted secondary use of health data for innovation and compliance.

CONSORTIUM APPROACH

Utilizing Privacy-Enhancing Technologies (PETs), trusted data-sharing infrastructures, and verifiable AI to ensure structured, safe, and audit-ready RWD for regulatory use.

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Technical Goals

R&D FUNDING

1. PRIVACY-PRESERVING DATA ENRICHMENT

Develop scalable PET-based pipelines (multi-party computation, federated learning, synthetic data, Zero-Knowledge Proofs) to securely prepare Real-World Data (RWD) for data-driven certification.

2. REGULATORY ALIGNMENT

Build verifiable, auditable workflows to support data reuse for MDR/CE/FDA compliance while strictly maintaining safety and efficacy standards.

3. DATA INTEROPERABILITY

Harmonize heterogeneous sensor, biomarker, and clinical datasets across multiple data spaces, ensuring ethical and lawful secondary use.

4. EQUITY & INCENTIVE MODELS

Implement mechanisms for SME participation, including shared value creation, infrastructure compensation, and equitable access to enriched data.

5. DEPLOYMENT & SCALABILITY

Enable cloud and edge deployment of PET-enabled pipelines, ensuring vendor-neutral, flexible, and reusable infrastructures for MedTech innovators.

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Expected Impact

R&D FUNDING

CORE PRODUCT OUTCOME

A privacy-preserving, PET-enabled data enrichment platform for data-driven MedTech certification, supporting MDR/CE/FDA compliance with structured, verifiable Real-World Data (RWD).

CLINICAL

Faster and more reliable regulatory approval enables safer, effective digital health solutions, accelerating patient access to innovative MedTech products.

ECONOMIC

Streamlined certification reduces time-to-market for SMEs, creates scalable infrastructure and tooling opportunities, and fosters equitable participation in AI-driven MedTech innovation.

SCIENTIFIC & IP

Standardized, verifiable data workflows generate high-impact publications, new digital biomarker benchmarks, and opportunities for patents and IP protection.

SOCIETAL

Enhances trust, safety, and accessibility of AI-driven MedTech, supporting innovation while aligning with SDG 3 (Good Health) and SDG 10 (Reduced Inequalities).

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Partnerships

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NEEDED PROFILES

SMEs / MedTech

With experience in digital health solutions and/or regulatory certification.

Research Institutes

With expertise in privacy or verification enhancing technology.

Clinical Partners

To provide real-world data contexts and validation environments.

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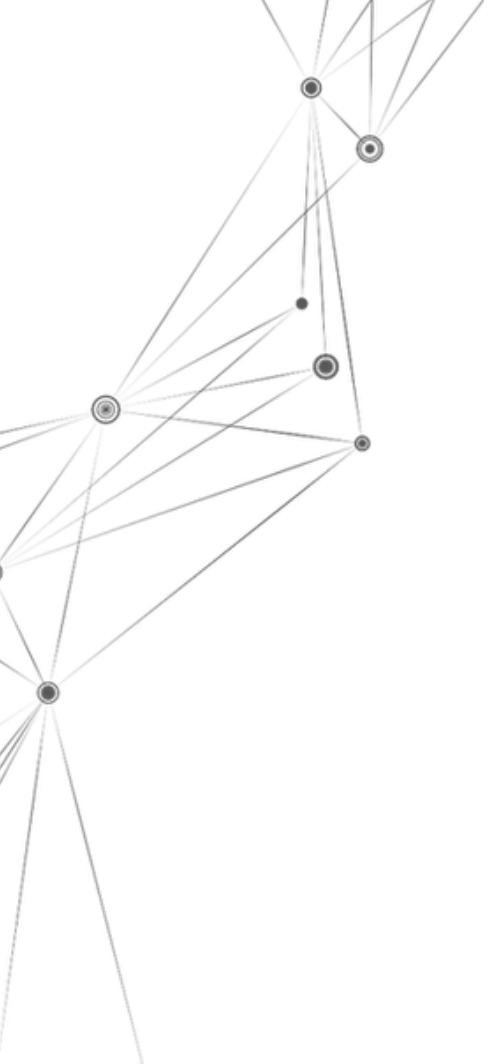

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