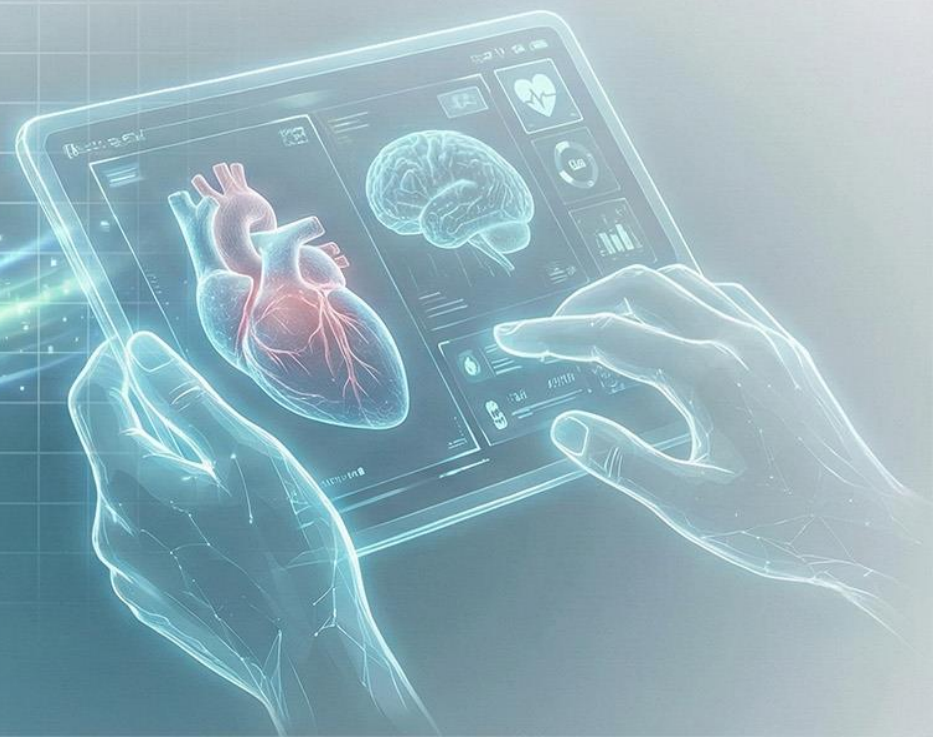


Regulatory Traceability Framework for Patient-Centred Health Technologies (REG-TRACE)

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Presented by: Şahin Mete



Regulatory Traceability Framework for Patient-Centred Health Technologies

REG-TRACE addresses the critical gap between rapid AI innovation and static safety regulations (MDR/AI Act).

We are establishing a Regulatory Science Sandbox to validate the "CARE-Framework," a novel certification methodology that ensures high-risk AI is safe, effective, and transparent.

Our approach replaces traditional, slow validation with dynamic evidence generation by utilizing:

- **Swarm Learning:** For privacy-preserving, decentralized model training.
- **Explainable AI (XAI):** To measure clinical trust and eliminate "black-box" risks.
- **Lifecycle Validation:** Using retrospective Real-World Data (RWD) to test continuous safety monitoring without the need for new clinical trials.



Implementation & Impact

1. The "Sandbox" Mechanism

We validate the CARE-Framework using a Retrospective Cardiovascular Risk Pilot, creating a safe environment for regulatory testing without patient risk.

- **Input:** Retrospective Electronic Health Records (EHR) & Biomarker data remain at clinical sites (Privacy-First).
- **Process:** Swarm Learning trains the AI across borders, while XAI modules generate decision logs.
- **Audit:** Notified Bodies "enter" the Sandbox to audit the learning process and traceability logs, not just the final algorithm.

2. Expected Outcomes

- **Regulatory Blueprint:** A validated "Guidance Document" for auditing decentralized AI under the MDR & AI Act.
- **Reduced Friction:** A standardized pathway that cuts certification time and costs for EU innovators.
- **Trustworthy AI:** A scalable model for ensuring patient safety and bias mitigation in high-risk medical software.

Our Expertise

Bewell Technology

- **R&D Excellence:** Extensive track record in Horizon Europe, ITEA, Celtic-Next (e.g., [TiDiT](#), [R-PODID](#), [DAIsy](#), [AICom4Health](#)), specializing in demonstrator-to-product transitions.
- **Digital Health & IoT:** Proven capability in custom embedded sensing and "Digital Shadow" concepts (tracking asset lifecycles), crucial for Post-Market Surveillance (PMS) data collection.
- **Secure Data Pipelines:** Expertise in end-to-end encryption and edge-to-cloud architectures, ensuring the data integrity required for regulatory audits.

Innova

- **Decentralized AI:** Technical mastery of privacy-preserving machine learning architectures (Swarm Learning, Federated Learning), enabling model training without data transfer.
- **Medical Analytics:** Established competency in Deep Learning for healthcare, specifically in Coronary Artery Calcium (CAC) scoring and segmentation of medical imaging data.
- **Privacy & Standards:** Experience in implementing Differential Privacy techniques and HL7 FHIR interoperability standards for clinical data integration.

By fusing **Innova's** proven capabilities in privacy-preserving AI architectures with **Bewell's** expertise in secure data pipelines, we create the complete technical foundation for a Regulatory Sandbox.

Partners Sought

Clinical & Validation Partners (The "Validators")

We invite clinical partners from medical domain to validate the CARE-Framework. We are looking for:

- **Hospitals & Clinical Centers:** With access to retrospective Real-World Data (RWD) in high-risk areas (e.g., chronic disease, imaging, or critical care).
- **Medical Research Institutes:** Seeking to test their own AI algorithms within a compliant, "Sandbox" environment.

Strategic Regulatory Partners (The "Auditors")

To complete the regulatory value chain and validate the sandbox:

- **Notified Bodies:** To co-define "audit-readiness" checklists and test the framework as a pre-certification tool.
- **HTA Bodies & Standardization Experts:** To translate technical metrics into policy guidance and reimbursement standards for the EU market.
- **Patient Advocacy Groups:** To co-design Patient-Reported Outcome Measures (PROMs) and validate AI "trustworthiness."

Technology Providers (The "Builders")

We invite diverse technology partners to expand the Sandbox's technical capabilities:

- **Innovative Tech Companies:** Partners with expertise in secure data infrastructure, cybersecurity, or novel AI modalities (e.g., NLP, Genomics) who wish to integrate their solutions into a regulatory-compliant framework.

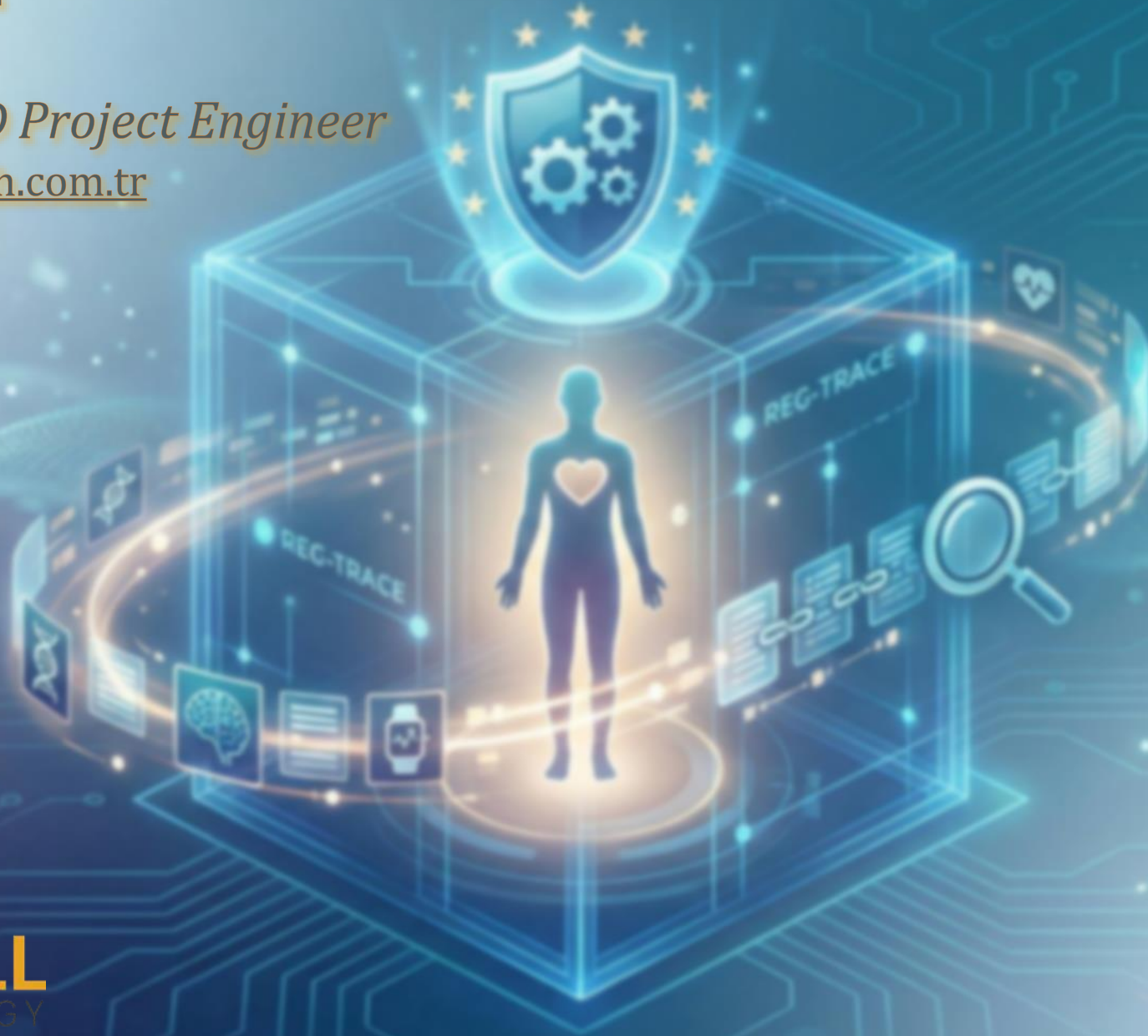
Contact details:

Şahin Mete, *R&D Project Engineer*

sahin.mete@bewelltech.com.tr

+90 553 745 46 59

+90 222 290 25 33



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