Scaling a US-Validated Automated Registry Model to Europe

Using National Digital Health Maturity as a Market Readiness Framework for Site-Level Real-World Evidence Generation

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Objectives

- **The model:** A US-validated, **artificial intelligence (AI)-enabled registry platform** leveraging natural language processing (NLP) and multi-source data harmonization for **automated electronic health record (EHR) data capture** across multiple therapeutic areas.
- **The objective:** Evaluate the European Commission's (EC) **2025 Digital Decade composite eHealth indicator** as a proxy for digital health ecosystem maturity, and establish an **EU market readiness framework** for scaling automated EHR-enabled registries.

Methods

1 DATA SOURCE

2025 Digital Decade eHealth Indicator report

- **29** countries (EU-27 + Iceland, Norway)
- **12** sub-indicators + composite score
- **4** thematic domains

2 MAPPED TO SITE-LEVEL PREREQUISITES

Derived from the **ISPOR EHR data SUITABILITY framework** (Fleurence et al., 2024)

EC DIGITAL DECADE		ISPOR SUITABILITY
Ecosystem maturity		
Overall composite score	1	**Governance & legal readiness**
Data digitization		
Provider connection rates	2	**Care setting & site coverage**
Category completeness		
Core clinical data availability	3	**Data reliability & completeness**
Format standardization		
Interoperability	4	**Data curation, ETL & CDMs**
Data currency		
Data availability & timeliness	5	**Data timeliness & temporal relevance**

3 STRATIFIED BY EC TAXONOMY

Trendsetters	**≥90%**
Fast-trackers	**82–89%**
Followers	**70–78%**
Beginners	**<70%**

Composite eHealth indicator cut-offs

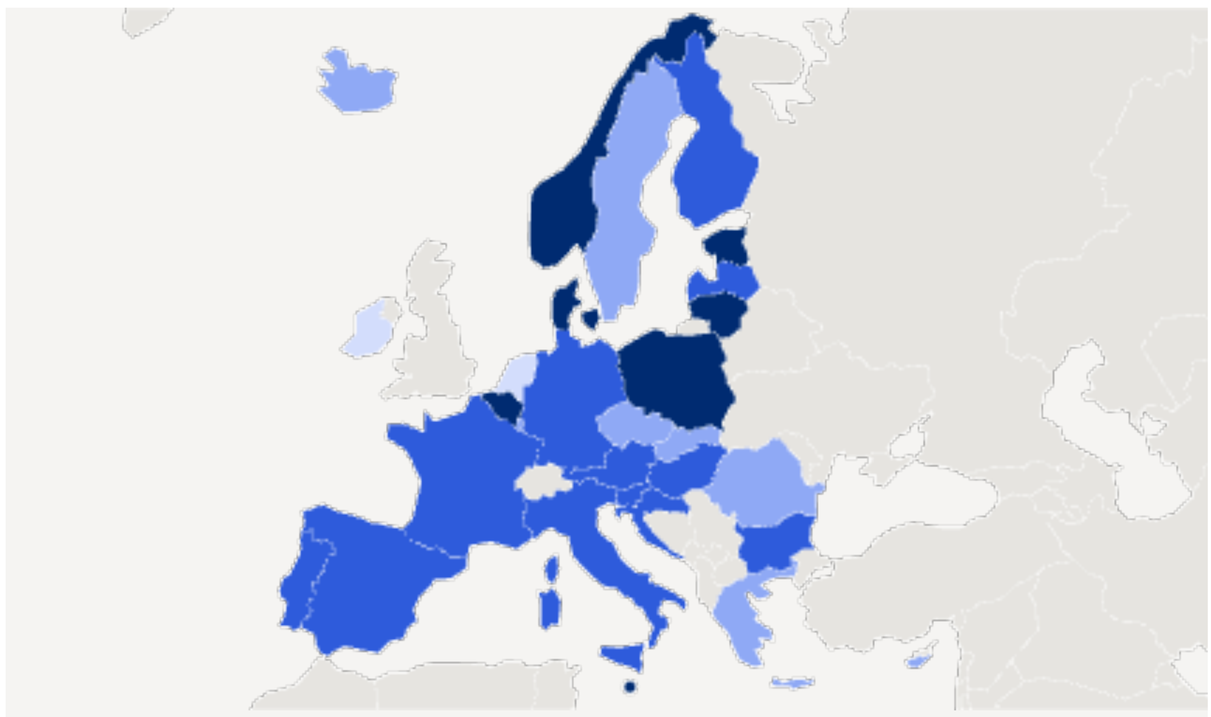
Results

MARKET READINESS BY COMPOSITE EHEALTH INDICATOR

Trendsetters · 7 countries — Highest readiness

Most conducive to **direct deployment of automated EHR-based registry infrastructure**

Belgium | **Estonia** | **Denmark** | **Lithuania** | **Malta** | **Poland** | **Norway**



Trendsetters ≥90% (7) · **Fast-trackers** 82–89% (12) · **Followers** 70–78% (8) · **Beginners** <70% (2) · Not assessed

Variation across major economies

The five largest EU economies cluster in Fast-tracker or lower tiers, demonstrating that economic scale alone does not dictate digital health maturity.

Tiers by composite eHealth indicator, 2025 Digital Decade eHealth Indicator Study (EU-27, Iceland, Norway). Malta shown as dot. [1]

DATA CATEGORY MATURITY

Highest maturity

ePrescription / eDispensation (average) — **88%**

Laboratory results — **84%**

Hospital discharge reports — **82%**

Broad availability of **structured clinical data for automated extraction** in top-tier markets.

Lowest maturity

Medical device data — **55%**

Medical imaging — **26%**

Lowest across **all tiers**—requires **supplementary collection strategies** regardless of country readiness.

POLICY CONTEXT

The **European Health Data Space (EHDS) Regulation (2025)** strengthens the mandate for cross-border health data standardization; adoption of common **interoperability standards** is expected to accelerate Fast-tracker transition into Trendsetters and reduce cross-border RWE harmonization friction.

Conclusions

Pragmatic benchmark

The composite eHealth indicator offers a standardized basis for evaluating European registry site readiness.

Targeted rollout

Stratification supports country prioritization for multi-country RWE programs; Trendsetters offer the most direct path to automated registry deployment.

Implementation roadmap

Informs deployment planning under EHDS and the evolving HTA landscape; imaging- and device-heavy studies require hybrid capture across all tiers.

CONFERENCE
Presented at ISPOR EU 2026, Vienna, Austria.

REFERENCES
1. European Commission. 2025 Digital Decade eHealth Indicator Study – Final Report. Capgemini Invent; 2025. DOI: 10.2759/2737039.
2. Fleurence RL, et al. Assessing Real-World Data From Electronic Health Records for Health Technology Assessment: The SUITABILITY Checklist. Value Health. 2024;27(6):692–701.

ABBREVIATIONS
AI, artificial intelligence; CDM, common data model; EC, European Commission; EHDS, European Health Data Space; EHR, electronic health record; ETL, extract, transform, load; EU, European Union; HTA, health technology assessment; NLP, natural language processing; RWE, real-world evidence.

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