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# **Blended Digital Data Spaces:** a brief retrospective analysis of sharing data between European countries

From EDIFACT to the European Health Data Space (EHDS)

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A large red triangle pointing to the right, located at the bottom left of the slide.



- From Envelopes to Meaning
- From Pilots to Infrastructure
- Policy & Trust at Scale
- AI for Blended Digital Data Spaces
- Preparing Execution Playbook



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## **Part I — From Envelopes to Meaning (EDIFACT → epSOS origins)**

# Why data exchange matters?



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- Continuity of care across borders (planned & unplanned)
- Safer medicines: allergies, interactions, ePrescriptions
- Research & public health: from silos to federated insights
- Interoperability is layered: syntax, semantics, governance

# EDIFACT Era: the grammar of early exchange



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- UN/EDIFACT (ISO 9735): common syntax for structured messages
- Pervasive in European industries, incl. healthcare admin/claims
- **Strength:** rigorous syntax and directories;
- **Limit:** clinical semantics

# Early Clinical Standards

From syntax to meaning: the early patchwork:



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- . Parallel **clinical standards grew**: HL7 v2, CDA; DICOM for imaging
- . **Europe** worked on EN/ISO 13606 for EHR communication
- . **Outcome**: islands of compatibility, not yet a continent

# Smart cards: national successes, European fragmentation



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- **France:** SESAM–Vitale;
- **Germany:** eGK;
- **Italy:** Tessera Sanitaria
- Secure microchips, PKI, and local workflows—  
strong national adoption
- **But no EU-wide clinical payload** or common  
reader/use model

# The 'European Carte Vitale' that wasn't



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- **EHIC** (2004) unified entitlement proof—but no clinical data on chip
- Projects like **NETC@RDS** piloted online entitlement verification
- A pan-EU clinical smart card proved politically and technically elusive

# What blocked early EU-wide sharing?



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- **Legal fragmentation pre-GDPR**; uneven data protection interpretations
- **No common trust framework** for digital identity/signatures (pre-eIDAS)
- **Semantic gaps**: SNOMED CT licensing, LOINC coverage, language variants
- **Uneven infrastructure & EHR uptake**; limited funding & governance



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## **Part II — From Pilots to Infrastructure (epSOS → MyHealth@EU)**



- Chose two cross-border services: Patient Summary & ePrescription
- Used HL7 CDA + IHE profiles (XCPD/XCA/XDR) to broker exchange
- Set the template for today's cross-border services



- National Contact Points for eHealth (NCPeH) as gateways
- Today: Patient Summary & ePrescription live in multiple states
- Roadmap extends to more data types over time



- eHealth Network guidelines: common content & safety focus
- **Terminologies:** SNOMED CT, LOINC, ATC; controlled vocabularies
- **New services** increasingly align to HL7 FHIR implementation guides

# Today's standards momentum: FHIR for Europe



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- HL7 Europe releasing EHDS-aligned FHIR Implementation Guides
- MyHealth@EU waves plan FHIR-based services (e.g., labs)
- FHIR = granular APIs → better reuse across care & research



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## Part III — Policy & Trust at Scale

# EHDS: the policy breakthrough (2025 → ...)



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- Entered into force in 2025; transition & implementing acts ahead
- **Primary use:** citizens' electronic access & cross-border continuity
- **Secondary use:** Health Data Access Bodies & permits for research/innovation



- Regulation (EU) 2024/1183: EU Digital Identity Wallets
- Trust anchor for verified credentials (incl. health-related attestations)
- Potential bridge: identity, consent, and cross-border authorisation

# What changes now vs. the 2000s?



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- **Legal clarity:** GDPR + EHDS; trust via eIDAS 2.0
- **Technical convergence:** FHIR, IHE, shared terminologies
- **Operationalisation:** NCPeH network, EU funding & procurement
- **Cultural shift:** citizen access by default; portability as a right



- **Unplanned care abroad:** allergies, meds, diagnoses—instantly accessible
- **Planned care:** ePrescriptions/eDispensation without paper detours
- **Rare diseases:** cross-border expertise and longitudinal data



- **Secondary use** under EHDS: transparent permits & governance
- **Federated analysis:** bring algorithms to data, not data to algorithms
- Real-world evidence, safety monitoring, crisis response



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## **Part IV — AI for Blended Digital Data Spaces (Beyond Translation)**

# AI's Role in Cross-Border Health Data: Beyond Translation



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- Language is no longer the main barrier → semantics, policy, and workflows are
- GenAI helps interpret, adapt, and mediate—but must be governed
- Goal: explicit, computable localization on top of shared FHIR/IHE standards



- **The tree:** real-time, high-quality translation and summarisation
- **The forest:** semantic interoperability, coding rules, clinical culture, reimbursement
- **Focus:** from 'same words' → 'same meaning' → 'safe, lawful use'

# What GenAI Enables Today (Safely)



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- **Multilingual** discharge summaries with controlled medical glossaries
- **Terminology** suggestions and unit normalisation (SNOMED/ICD/LOINC/ATC) with uncertainty
- **Guideline** comparison (e.g., ESC vs NICE) with contextual adaptation and citations
- **Data-quality checks:** temporal anomalies, duplicates, PHI detection for de-identification

# What AI Does NOT Solve Automatically?



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- . Different coding and billing regimes shape documentation
- . Variable availability of services changes 'reasonable next steps'
- . Divergent legal bases for processing, consent, and retention
- . Risk of plausible but wrong 'hallucinations' without grounding

# Make Differences Explicit (Not Uniform)



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- **Localisation layers:** terminologies, thresholds, policies, roles
- Represent as 'context packs' per country/discipline
- Execute with policy-as-code controlling access, masking, and logging

# 10 High-Value GenAI Uses in Blended Data Spaces (1/2)



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1. **Assisted semantic mediation:** mapping SNOMED↔ICD, LOINC↔local with confidence
2. **Country-aware clinical summaries:** add relevant legal/clinical context
3. **Guideline bridging:** highlight gaps, justify local adaptation with citations
4. **Process mining** to local checklists from FHIR event logs
5. **Natural-language cohort queries** → federated FHIR/OMOP requests

# 10 High-Value GenAI Uses in Blended Data Spaces (2/2)



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1. **Data quality:** detect anomalies, PHI, inconsistent units
2. **Patient experience:** constrained translation + teach-back verification
3. **Policy-aware interop:** apply consent and legal bases as executable rules
4. **Coding assistance:** suggest diagnosis/procedure codes with explanations
5. **Synthetic data** 'digital twins' for testing cross-border flows



- **EU AI Act:** classify use-cases; maintain a safety case; monitor bias and performance
- **GDPR & EHDS:** data minimisation, purpose limitation, auditability, lawful bases
- **MDR** (where applicable): clinical risk management and post-market surveillance
- **Operational controls:** RBAC, grounding/RAG, prompt policies, immutable logs



- **Base:** MyHealth@EU + FHIR/IHE + terminology services
- **Policy layer:** consent, purposes, retention → policy-as-code
- **Context packs:** per country/speciality thresholds, coding, workflows
- **AI orchestrator:** RAG over official sources; agents for mapping/guidelines/policy; human-in-the-loop
- **Observability:** metrics, error dashboards, feedback to governance



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## **Part V — Preparing Execution Playbook (KPIs, Scale-Up)**

# Lessons learned from the 'smart card' era



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- **Hardware ≠ interoperability:** focus on data models and services
- **Interoperability is socio-technical:** laws, workflows, funding matter
- **Start** with narrow, high-value services and iterate (epSOS playbook)



- **Syntactic:** HL7 FHIR/IHE; Semantic: SNOMED, LOINC, ATC
- **Governance:** NCPeH, Health Data Access Bodies, auditability
- **Trust:** eIDAS wallets, consent receipts, security by design



- **Map** local data to EU profiles (Patient Summary, eRx, labs)
- **Invest** in terminology services & translation pipelines
- **Pilot** cross-border flows via NCPeH; measure safety & time-to-info
- **Prepare** for secondary use: de-identification & federated analytics



- **Clinical:** avoided medication errors; time-to-information; re-admissions linked to missing info
- **Data:** mapping coverage; semantic discrepancies; terminology completeness
- **User:** clinician acceptance (% unchanged outputs); time saved; adoption rates
- **Compliance:** blocked violations; audit completeness; review cycle time
- **AI quality:** accuracy by language/subgroup; false-alert rate; explainability score



- **From multilingual to multi-context:** AI helps adapt data to local meaning and law
- **Make differences explicit and computable;** keep humans in the loop
- **Start small, measure hard, scale what works—**without losing traceability