



European Health Data Slice and the evolving European Health Data Space and the use case of the PAROMA-MED Project

Pooja Mohnani, Project Manager, Eurescom GmbH

contact@paroma-med.eu

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- Views and opinions expressed, are those of the author(s) only and do not necessarily reflect those of the European Union or the European Commission (granting authority). Neither the European Union nor the granting authority can be held responsible for them.

The Shift Toward Data-Driven, Human-Centered Healthcare in Europe

Growing emphasis on preventive, personalized, and precision medicine
Rising need for health data to inform research, innovation, and public health
Cross-border healthcare requires harmonized data infrastructures
Citizens demand greater control over their health data

Vision of the European Health Data Space (EHDS)

•EU initiative to create a unified framework for health data access and exchange •Supports both primary use (individual care) and secondary use (research, policymaking)

•Builds trust through strong data governance and citizen-centric control



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EHDS: Key Principles

Core Features of the EHDS



- Interoperability across national and regional health systems
- Data security and compliance with GDPR
- •Citizen empowerment and consent-driven data usage
- •Support for innovation in AI and digital health

What is a Health Data Slice?

- A thematic or project-specific implementation of EHDS principles
- Offers federated, secure, and policy-aligned data access
- Enables cross-border research while preserving local data governance
- Accelerates specific use cases (e.g., rare diseases, personalized medicine)

Data Ecosystems with 6G

- New capabilities to exploit
 - Terabit-per-second data rates and ultra-low latency
 - Enhanced automation, flexible deployments, and end-to-end slicing techniques.
- Expected impact
 - New application in high-capacity sectors: healthcare, augmented reality, IoT.
 - Secure, private bandwidth for critical systems like Electronic Health Records (EHR).
- Proposed innovations
 - Functional GDPR Approach
 - Continuous transparency and automated privacy validation.
 - Moving beyond accountability to proactive data flow control.



User-centric tools: push notifications, wallet apps, assisted consent management. Empowerment through transparency and control over data rights. Simplified interfaces for informed decisions and data monitoring.

Data Scientist

Data Subject

- Access to rich, high-quality data using FAIR principles.
- GDPR-compliant workflows with continuous consent enforcement.
- Al models treated as data assets with a managed lifecycle.

Health Experts

- Empowering physicians with control over metadata creation.
- Metadata as assets: linked to ownership, consent, and traceability.
- Enhanced insights via ML-based processing.

Businesses and Health Organizations

- Edge-based Horizontal Federated Learning to ensure data privacy.
- Secure local processing with data shared only among verified modules.
- Balancing data monetization with privacy compliance and accountability.

Stakeholder Roles and Needs in Data Utilization





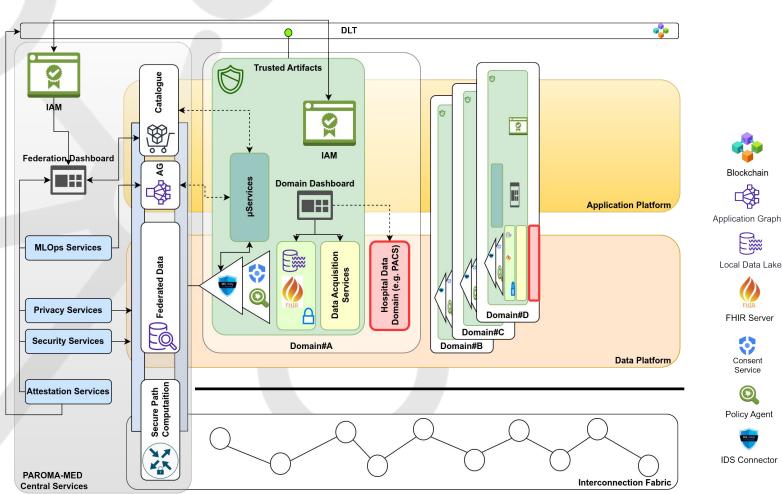


PAROMA-MED and Data Spaces Ready Approach

- Take advantage of Data Spaces features:
 - Enable data sharing while maintaining sovereignty principles.
 - Address healthcare-specific challenges like GDPR variations and market fragmentation.
- Apply as core principle:
 - Eliminate actual private data exchange while enabling in-place data processing.
- With overall goal:
 - Support scalable, privacy-respecting Healthcare Data Spaces.
 - Ensure data utilization aligns with user-defined consent options.

PAROMA-MED Architecture

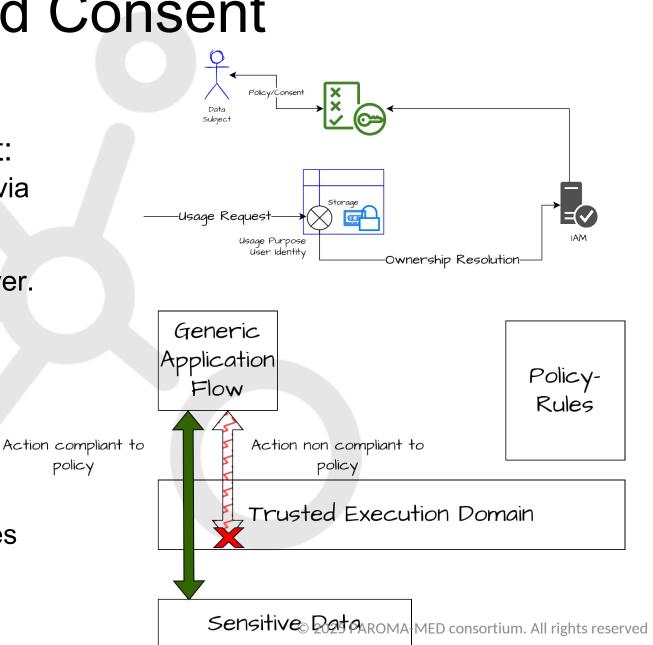
- Hybrid Cloud Design:
 - Combines centralized and decentralized components for domain sovereignty and transparency.
 - Supports compliance with current and evolving legislation.
- Layered Structure:
 - Interconnection Layer: Secure Path Computation for controlled data flow.
 - Data Layer: Federation and ergonomic tools for sovereign data management.
 - Application Layer: Simplified deployment, operation, and monitoring with privacy preservation at its core.



Data Protection and Consent Management

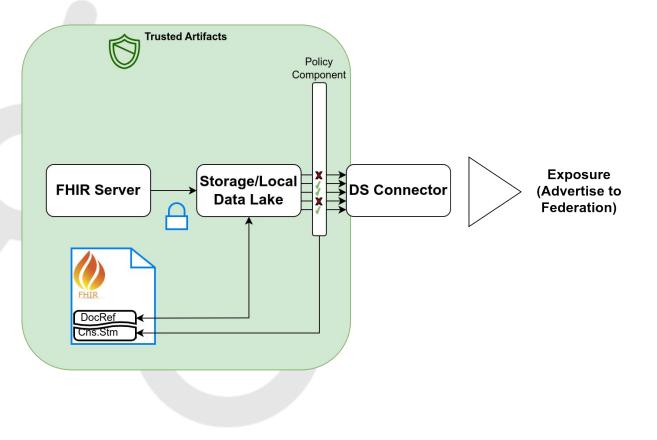
policy

- Dynamic Consent Management:
 - Notifications for missing consent via wallet or web dashboard apps.
 - Consent statements govern data use, enforced by a Protection Layer.
- Protection Layer Roles:
 - Validate adherence to consent policies.
 - Block non-compliant actions dynamically.
 - Enable updates to consent policies as needed.

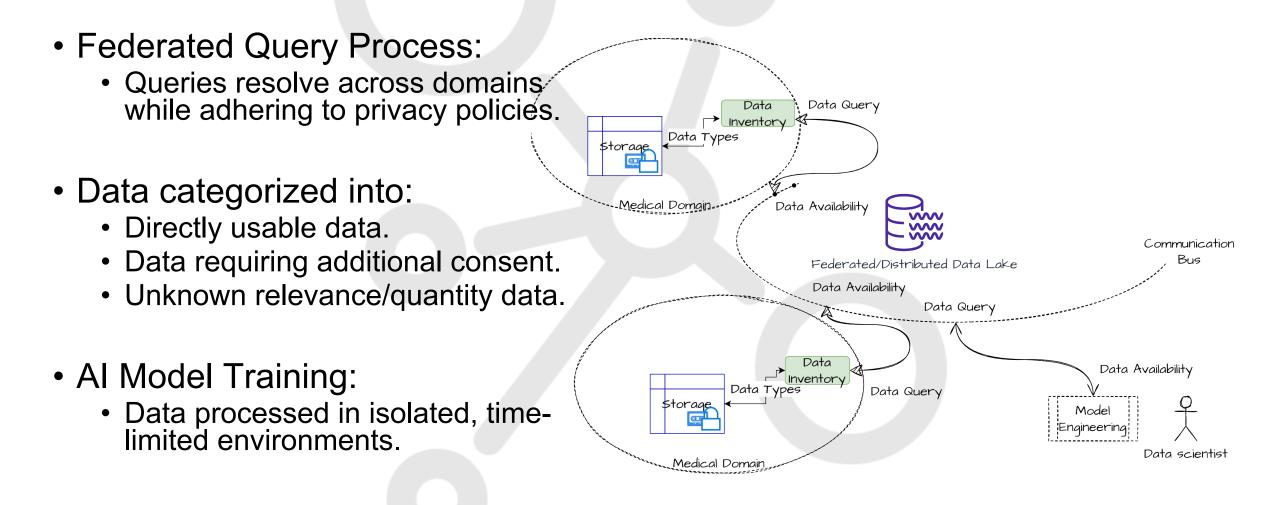


Data Exposure Approach

- Fast Healthcare Interoperability Resources (FHIR) server combined with secure object storage.
- Constraints from policies indicated by the individual consents are applied and the result updates are pushed through the Data Space Connnector



Enabling Federated Learning



Security and Privacy Framework

- Privacy-by-Design:
 - Identity and Access Management (IAM), anonymization and OpenID Connect (OIDC).
 - Role-Based (RBAC) and Attribute-Based (ABAC) access control models.
- Zero Trust Security:
 - Comprehensive protection for APIs, data handling, and federation partners.
 - Privacy-preserving data storage and processing across borders.

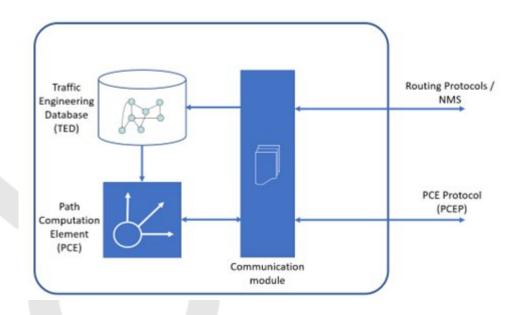
• Key Benefits:

- Automated federation partner attestation.
- Federated identity and access management.
- Flexible and secure access to private data while ensuring user preferences and regulatory compliance.



PAROMA-MED Network and Interconnect Platform

- Path Computation Element (PCE):
 - A specialized network entity for:
 - Dynamic path computations optimizing network performance.
 - Gathering data from Network Management Systems (NMS) for enhanced routing.
- Key Features:
 - Supports multi-layer networks with Quality-of-Service (QoS) guarantees.
 - Security, privacy, performance, and traffic volume constraints.
- Innovations:
 - Patent-protected framework: "Path Computation in a Communication Network."
 - Advances beyond traditional bandwidth/latency paradigms.
 - Tailors network slices for secure, private, and trustworthy 5G/6G communications.



Implementation Status

- Core Architectural Integrations:
 - Dataspace Connector
 - Built on Eclipse Dataspace Components.
 - Incorporates Dynamic Attribute Provisioning Service and Broker Extensions for proof of concept.
 - FHIR Server (HAPI-FHIR):
 - Coupled with a production-grade object storage solution.
 - Integrated with DICOM backends for seamless data ingestion.
 - Consent Management System:
 - Manages consent options for each field of personal and medical data.
 - Enables tailored configuration for diverse use cases.
 - Application in Federated Learning:
 - Utilizes consent options for data advertisement via Dataspace Connectors.
 - Supports contract negotiation for GDPR-compliant data provisioning.
- Pilot Success and Next Steps:
 - Proof of Concept: Demonstrated effectiveness in federated learning scenarios.
 - Future Workshops: Evaluate performance with citizens and medical experts.



PAROMA-MED Privacy Aware and Privacy Preserving Distributed and Robust Machine Learning



Thank you!

PAROMA-MED partners



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THALES Building a future we can all trust











