

# POLICY BRIEF FOR STANDARDIZING RISK FACTORS FOR DEMENTIA AND FRAILTY



## Executive summary

As Europe's demographic landscape shifts, the rising prevalence of dementia and frailty has become a critical stress test for national healthcare systems. The European Health Data Space (EHDS) is an attempt to respond to the fragmentation challenge, aiming to unleash health data for innovation and better patient care. However, a fundamental roadblock remains: researchers currently define study populations and collect data on patient risk factors in isolated silos using localized protocols. For policymakers, the challenge is ensuring that research yields actionable, scalable intelligence. This brief proposes a transition to a Harmonized Semantic Framework. By organically connecting the clinical objectives of specifying the exact inclusion and exclusion criteria with recommendations for precise semantic standards (like SNOMED CT) and structural data models (like HealthDCAT-AP), we can convert fragmented research into the high-quality, interoperable data required to train Artificial Intelligence (AI) and inform EU-wide precision policy.

## INTRODUCTION

As patient populations grow, the demand for precision medicine and AI-driven interventions requires high-quality, standardized data—a resource that is currently scarce due to fragmented research practices. The core issue is the lack of standardized clinical protocols in cross-border research. Currently, significant variance exists in how different European regions define risk factors for dementia and frailty.

In standard practice, researchers typically conduct an analysis of risk factors and inclusion/exclusion criteria in isolation, optimizing protocols solely for their specific local hypotheses. While this ensures internal validity, it creates significant data silos. These isolated pools of information do more than just hinder the training of robust AI models; they prevent us from informing EU-wide policy, severely limit the potential for technological breakthroughs in patient care, and restrict the delivery of precision medicine.



### THE SEMATIC INTEROPERABILITY GAP

Most protocols prioritize technical connectivity while neglecting semantic interoperability. Semantic interoperability refers to the ability of different information systems to not only exchange data but to accurately interpret, understand, and preserve the meaning and context of the data being shared.

To overcome this, clinical focus areas must dictate the exact inclusion and exclusion criteria we monitor, which must then be standardized into a common semantic language.

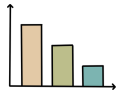
# APPROACHES & RESULTS



## Approaches

The findings in this brief are derived from activities within Task 2.3 of the COMFORTage project, which revealed critical gaps in the state-of-the-art. This task was devoted to unpacking a research methodology for the specification of key risk factors towards developing dementia and frailty. A primary goal was to specify the exact inclusion and exclusion criteria for study participation—such as age, gender, race, ethnicity, type and stage of disease, and previous treatment history.

Through a dual approach of literature reviews and several focused meetings, it became evident that persistent collaboration between clinical and technical partners is often missing in standard research designs. To resolve this, the project acted accordingly through collaborative efforts to agree upon mandatory fields and common elements for investigation plans, mapping knowledge and models directly to the data.



## Results

We learned that to ensure high-quality data necessary for AI model developments, policymakers must approach research design through a structured presentation. We identified four distinct conceptual layers:

We recommend explicit alignment with existing European metadata initiatives by integrating precise metadata standards like HealthDCAT-AP. Furthermore, aligning semantic interoperability frameworks with the FOXS stack is highly recommended to ensure Health Data remains FAIR.

### **Structural Aspects**

To ensure the collected risk factors and demographic data are aggregable, we recommend the integration of stratified clinical terminologies proposed by SNOMED CT. This prevents ambiguous free-text and assigns precise semantic codes to every inclusion criterion.

### **Semantic standards**

We must standardize how variables are collected. We learned this requires enforcing Common Data Elements (CDEs) through a standard "Minimum Common Data Set".

### **Methodological tools**

Research must clearly define the clinical objectives, risk factors, comorbidities, and prevention stages. This includes defining the exact inclusion and exclusion criteria for study populations.

### **Clinical Elements**



## Conclusion

Implementing these standardized protocols does more than just tidy up data; it is the engine for innovation. We conclude that explicitly mapping how a risk factor moves from a defined inclusion criterion, to a recommended semantic standard, and into a structural model is the only way to break down regional data silos. High-quality, harmonized data is the prerequisite for robust AI model training and accurate analysis, directly feeding into cutting-edge tools such as Patient Digital Twins for predicting health trajectories, Virtual Coaches for daily guidance, and Clinical Decision Support Systems for diagnosis.

## Implications and recommendations

If the current fragmented approach continues, the EHDS will struggle to reach its goals, and isolated data will continue to stifle medical breakthroughs. Conversely, this shift enables a "Precision Policy" approach that transforms raw data into personalized care pathways, ensuring the delivery of tailored prevention models so that every European citizen receives the right support at the right time.

To transition from fragmented research to a unified European Health Data Space, policymakers must mandate a structured workflow for protocol creation. We propose four high-impact actions:



### **Mandate Multi-Stakeholder Co-Design:**

Involve patients, caregivers, and clinicians from Day 1 to ensure research addresses real burdens, yielding high social impact.



### **Adopt a Prevention-Stage Framework:**

Categorize digital interventions by Primary, Secondary, or Tertiary prevention stages to ensure digital pathways match specific disease stages.



### **Enforce Common Data Elements (CDEs):**

Mandate a standard "Minimum Common Data Set" for risk factors and comorbidities so data from different regions uses the same "language" to be aggregable for AI models.



### **Establish Adaptive Ethical Governance:**

Create a "Living Guideline" repository for ethical and risk analysis templates to simplify compliance and reduce administrative bottlenecks across different prevention stages..