

IHI Call Days | Call 12

Accelerating Real-world evidence through Continuous Harmonization - ARCH

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Challenges

- European Health Data Space (EHDS) aims to “provide a consistent, trustworthy, and efficient system for reusing health data for research, innovation, policy-making, and regulatory activities”, but faces two primary challenges to realizing this potential:
 - **Data standardization** across the diversity of health data across Europe: different patient populations across various geographies, capturing data elements from an array of disparate data capture processes (electronic health records, administrative claims, registries) within and across primary, secondary specialty, and inpatient care settings
 - **Standardized analytics** to consistently and reproducibly apply scientific best practices and appropriate statistical methods for clinical characterization, causal inference, and machine learning across a distributed network of European databases

Your approach to solve the problem

- Accelerating Real-world evidence through Continuous Harmonization (ARCH) will address these challenges and address the unmet public health need within IHI specific objective 4: exploiting the full potential of digitalization and data exchange in healthcare, by:
 - Increased efforts to **standardize existing data sources** to the OMOP Common Data Model, building on the work initiated by the IMI European Health Data and Evidence Network (EHDEN) project, supported by the OHDSI global open science community, and continued within European Medicines Agency's (EMA) DARWIN-EU initiative
 - Creating public resources for **standardized vocabularies** and source vocabulary mappings and a phenotype library that is applicable and representative of European research needs
 - Developing certification for data partner '**readiness-for-research**' and education for 'real world data network science'
 - Delivering direct value to participating stakeholders through application of standardized analytics for '**Evidence-At-Scale**' across a European network

Is your project suitable for IHI?

- **Need of PPP:**

- Private partners bring expertise in the evidence needs, but collaboration is required to ensure data sources are ready-for-research and fit-for-use across the wide range of use cases
- Evidence-at-scale requires the breadth of a pre-competitive landscape review to examine all diseases or treatments
- Participation of regulators and academic researchers is necessary:
 - to ensure evidence is trustworthy and actionable in regulatory and clinical decision-making and
 - for their expertise in the source data, data science and informatics approaches to integrate data into analytic workflows
 - for filling the evidence gaps

- **Industry contribution**

- Involvement (in-kind and financial contributions) will allow greater research efficiency, access to data across multiple countries, and the ability to apply and influence standards that may be used within EHDS

Outcomes and Impact

- **Outcomes**

- Consistent and Standardized Data Understanding
- Robust and Dynamic Data Network
- Enhanced Phenotype Development and Evaluation
- Scalable Evidence Generation

- **Impact**

- Drive cross-sector health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe
- Expand access to research-ready real-world data and reliable real-world evidence
- Contribute towards the creation of an EU-wide health research and innovation ecosystem
- Improve quality and increased efficiency in real world evidence generation to support industry, regulatory and provider needs



Expertise and resources

- **IKOP from industry partners as:**

- Expertise from Epidemiology/ Medical Informatics, Data Standardization, Medical Vocabulary, Software Development, Health Economics & Outcomes Research, Market Access
- Financial contribution* to be used for funding third parties through subcontracting/ purchases of services mechanisms

*The financial contribution (FC) from industry beneficiaries will be allocated to the establishment of a fund, to support data standardization and evidence generation efforts among data partners not part of the initial applicant consortium

- **Support required from other partners:**

- Academic organizations and healthcare institutions with expertise and access to real-world data and real-world evidence generation capabilities
- Public partners with epidemiology / statistics / medical informatics expertise in phenotype development and evaluation, data quality assessment, and software development
- Organizations with expertise in data governance and procedures to adhere to EHDS regulations, including Health Data Access Bodies

Additional information

- IHI-ARCH initiative offers the opportunity to join a pan-European research network building on EHDEN, but with sharper focus on:
 - short-term ROI for industry
 - alignment with European regulators and HTA
 - broader data access.
- ROI for industry includes an international distributed network with standardized ETLs, centrally maintained vocabularies, and standardized analytics to align with and support DARWIN-EU and other regulatory/HTA activities