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# Deliverable Report for Milestone 2

## FAIR Data Spaces Demonstrator for Cross-Organizational Governance and Usage of Persistent Identifiers in Healthcare & Pharma for faster drug development

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# Introduction

The FAIR Data Spaces program is exciting and ground-breaking, because it helps to connect data from research and industry according to FAIR data principles to advance innovation and the digital transformation in various sectors.
We have described two use cases for a FAIR Data Space Demonstrator in the first milestone. We add a third use case in this milestone.
Additionally, we provide first results of the deployed ACCURIDS master data management platforms for the demonstration of use case 1.

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# **Use Case 3:** Drug Shortage Monitoring – Connecting Pharma with Health Authorities

**Challenge:** Due to the global disruption of supply chains, drug shortages have become a problem also for countries of the European Union, even for critical medicines.
To avoid drug shortages, health authorities such as the European Medicines Agency (EMA) or the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) collect information about the inventory of available medicinal products from pharmaceutical companies, hospitals and pharmacies.
The problem however is, that the information across the different organizations and European countries is not standardized which prevents health authorities from aggregating information effectively.
For example, the same product is marketed under different brands by different companies in different pack sizes with different strengths in different countries.
In addition, critical information on manufacturing locations, manufacturers, and input materials is not standardized or tracked, impeding proactive shortage mitigation efforts.

**Solution Outline:** The FAIR Data Spaces and ACCURIDS Registry with data standardization pipelines for medicinal product information provide a trusted and standardized infrastructure for harmonizing and sharing medicinal product data across stakeholders in the pharmaceutical supply chain.
The solution provides the following benefits:

1. *Harmonization of Master Data:* Establish a unified framework to standardize medicinal product data based on ISO Identification of Medicinal Products (IDMP) and the IDMP Ontology, including attributes for drug name, formulation, manufacturing locations, and materials.
2. *Trusted Data Exchange:* Implementation of HL7 Fast Healthcare Interoperability Resources (FHIR) using the FAIR Data spaces infrastructure in combination with FHIR messaging hubs for data exchange between participants using agreed upon reference and master data for contextualizing information in a standardized manner.

With this basis in place, health authorities can setup an inventory monitoring system based on standardized processes for real-time inventory tracking of critical medicines, leveraging FAIR-compliant infrastructure to detect and mitigate shortages proactively.

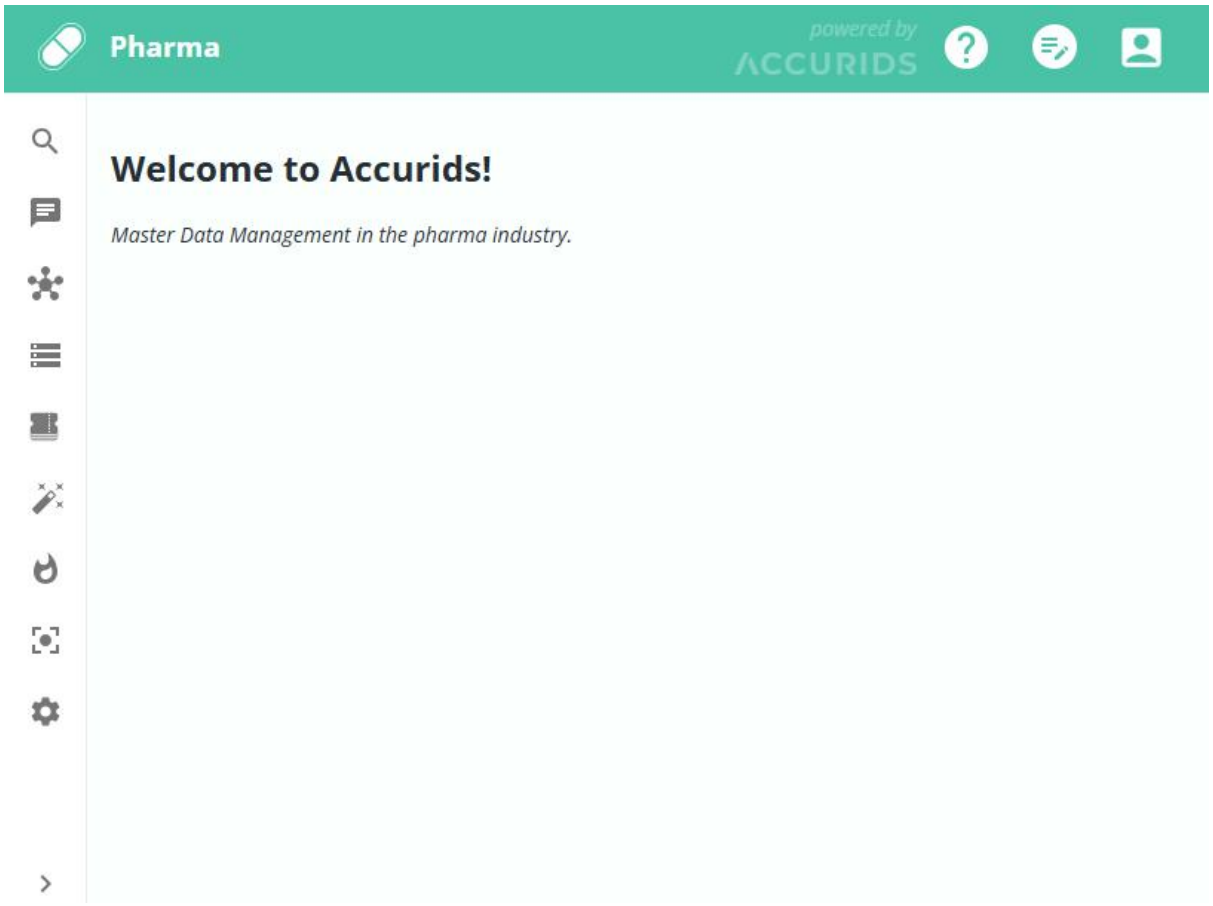
**Result:** We achieve drug shortage monitoring and drug shortage prevention based on standardized medicinal product data. The solution scales incrementally along multiple dimensions:
(a) *Scope of medicines:* We can start with critical ones and expand,
(b) *Jurisdictions and countries:* We can focus on a first marketed country and repeat for the next,
(c) *Scope of shared information:* We can start with the inventory of packaged medicinal products and expand to manufacturing and supply chain information.

# ACCURIDS Setup for Use Case 1

## Pharma Instance

We have one Accurids instance that represents the Pharma side of the demonstrator.

### Landing page




The landing page of the Pharma instance offers the standard layout and buttons as included in the Accurids platform out of the box.
We have added custom styles and logo to highlight the Pharma side.

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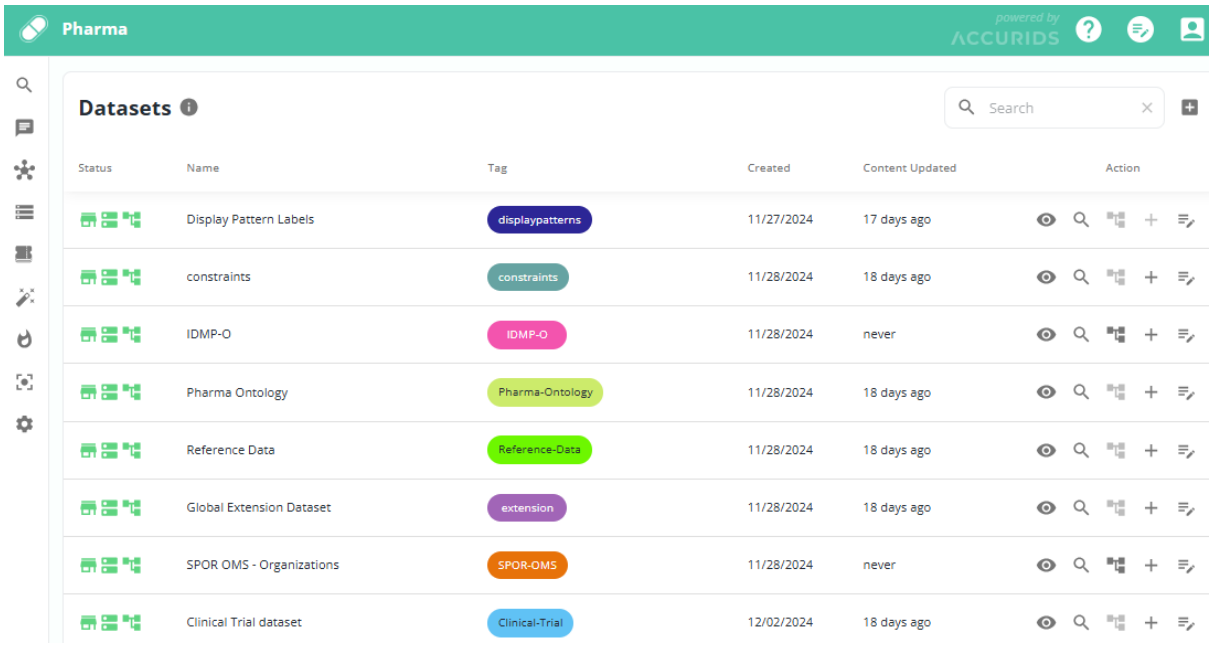
## Datasets



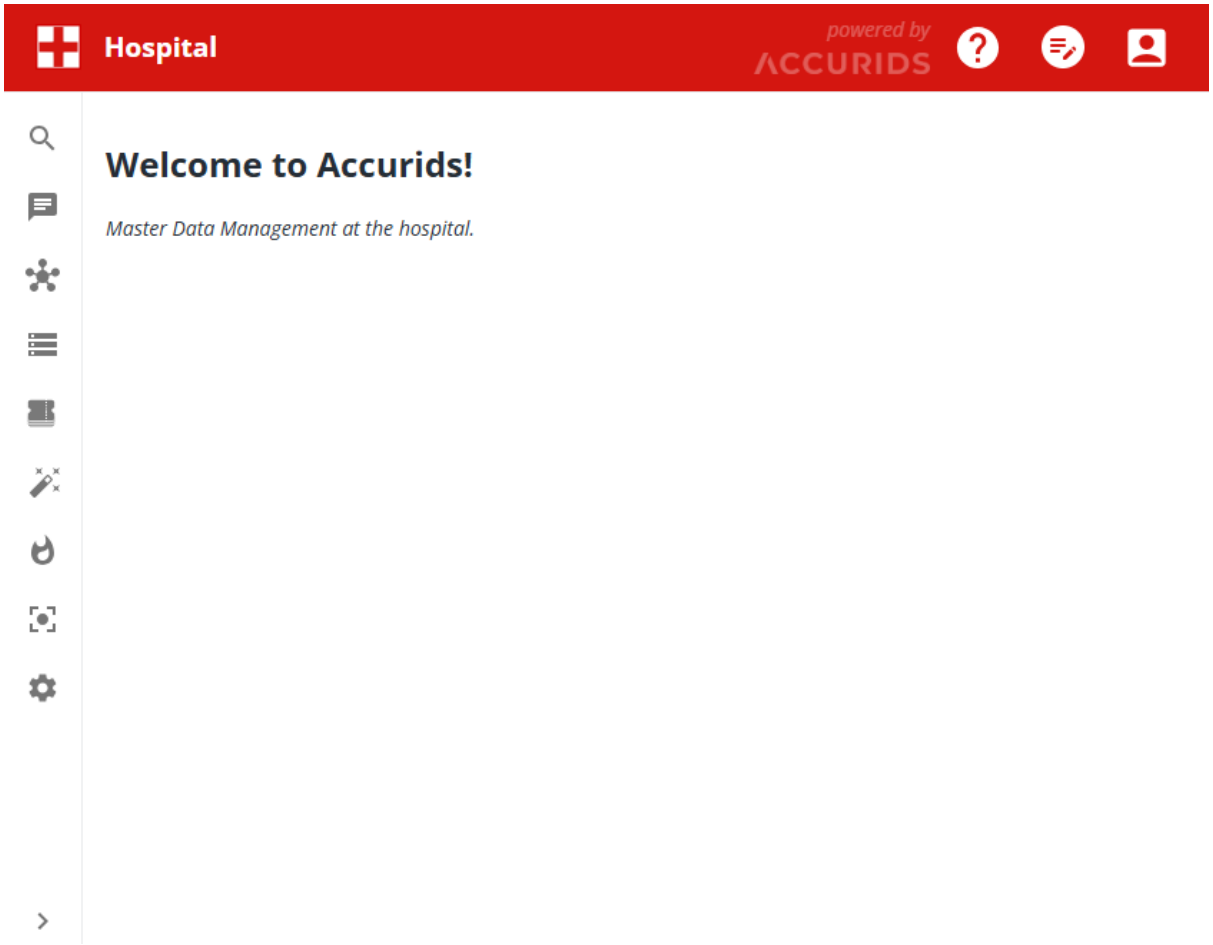

We have prepared the following datasets for demonstrating the use case:

- Pharma Ontology
  - It is the vocabulary of the Pharma company to describe information about clinical trials and human bio samples.
  - The Ontology contains terms like idmp-mprd:ClinicalTrial, pharma:TrialPhase, pharma:TrialSite, pharma:HumanBiosample.
    “pharma:” is the namespace of the Pharma company. The vocabulary can be aligned with public terminology like the IDMP-O (https://spec.edmcouncil.org/idmp/ontology). For example, the namespace “idmp-mprd:” belongs to the IDMP ontology.
- Reference Data
  - It is the standardized reference data from the Pharma company.
  - We include information like standard types of bio samples (e.g. cells, tissue, blood), typical phase of clinical trials (e.g. preclinical phase, phase 1, 2, 3, etc.)
- Public terminology
  - Interoperability and reusability are two of the core principles of FAIR data. Consequently, we reuse public terminology like IDMP-O, or standard SPOR datasets.
- Clinical Trial dataset
  - This dataset contains the Pharma information about the clinical trials. Our goal is to connect the clinical trial data with the information content coming from hospitals taking part in the clinical trial.
- Constraints
  - The dataset contains the specification of the information model of the Pharma company represented by data shapes following the SHACL specification.

## Hospital Instance

We have one Accurids instance that represents the Hospital side of the demonstrator.

### Landing page




The landing page of the Hospital instance offers the standard layout and buttons as included in the Accurids platform out of the box. We have added custom styles and logo to highlight the Hospital side.

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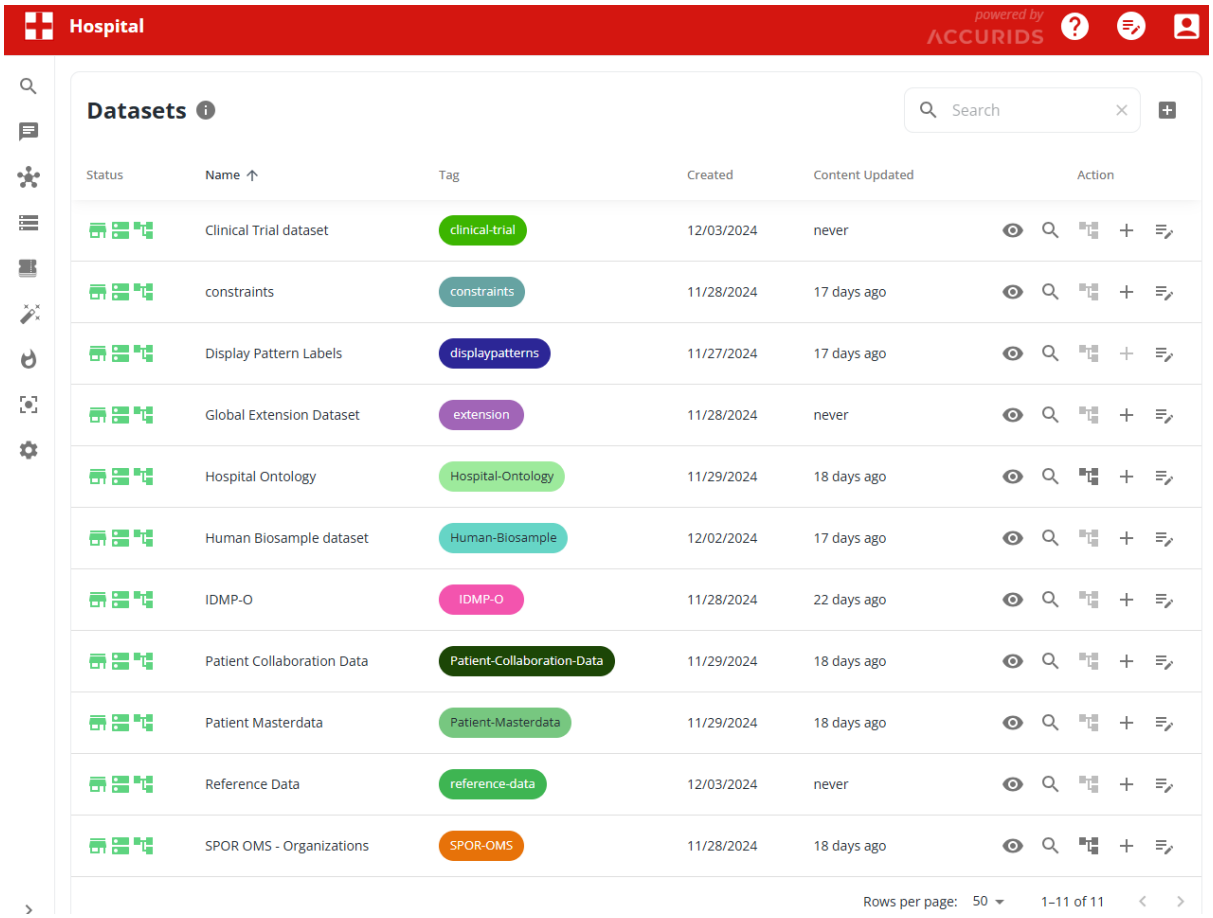
## Datasets




- Hospital Ontology
  - It is the vocabulary of the Hospital to describe information about patients and human bio samples.
- Patient Master Data
  - It is the personal information of patients in the hospital. Only anonymized information can be exchanged with external parties.
- Patient Collaboration Data
  - It is anonymized patient data that can be exchanged with external parties like the Pharma company.
- Constraints
  - The dataset contains the specification of the information model of the Pharma company represented by data shapes following the SHACL specification.