

A woman with dark hair tied back, wearing a white lab coat, is shown in profile, looking towards the right. She is holding a tablet computer. The background is a light blue gradient with faint, stylized hexagonal patterns and icons representing various technologies like Wi-Fi, a shield, a location pin, and a network diagram.

## Secure and Scalable Health Data:

*Making real world data actionable*

3rd Annual Meeting of the de.NBI Industrial Forum  
November 24<sup>th</sup> 2022 (virtual)

ITTM (IT for Translational Medicine) S.A.

27, Rue Henri Koch – House of BioHealth

L-4354 Esch-sur-Alzette, Luxembourg

Dr. Andreas Kremer , Co-Founder and Managing Director

# Disclaimer

*Dr. Andreas Kremer*

Co Founder and Managing Director of ITTM S.A.

Member of the Board of Directors of i2b2 tranSMART

Member of the ELIXIR Industry Advisory Committee

Expert for      ISO TC 276 “Biotechnology”;  
                      ISO/IEC JTC 1/SC 42 “Artificial Intelligence”;  
                      ISO TC 215 “Health Informatics”

Reviewer and Expert for the European Commission (incl. Ethics), EOSC-Life, and others

Overall, more than 25 years of experience in various positions with increasing responsibilities in Pharma and Clinical Research as well as Diagnostics.

<https://orcid.org/0000-0003-1466-0600>

## Data Management/Curation

(Pharma, pre-clin., clin. & RWD studies)

### Grants

IMI: TransBioLine, BioMap, ImSAVAR, ImmUniverse,  
T2EVOLVE, OPTIMA, EU-PEARL,

B2B: Pharma, Biotech, Registries, Hospitals, ...



Digital Health Services



Data Management/Curation

2018

## Digital Health Services

(RWD, PROM, PREM, ...) 

### Grants

H2020: Smart4Health, ICU4COVID, DigitalSkills4Health,  
COPreDict,

B2B: ParkinsonNet-LU, Com4Care (MVP),

Strategic Investment by POST Capital S.A. (LU)  
First Customers (B2B), First Grants (EIT, ITN)  
Incorporated and Operations started

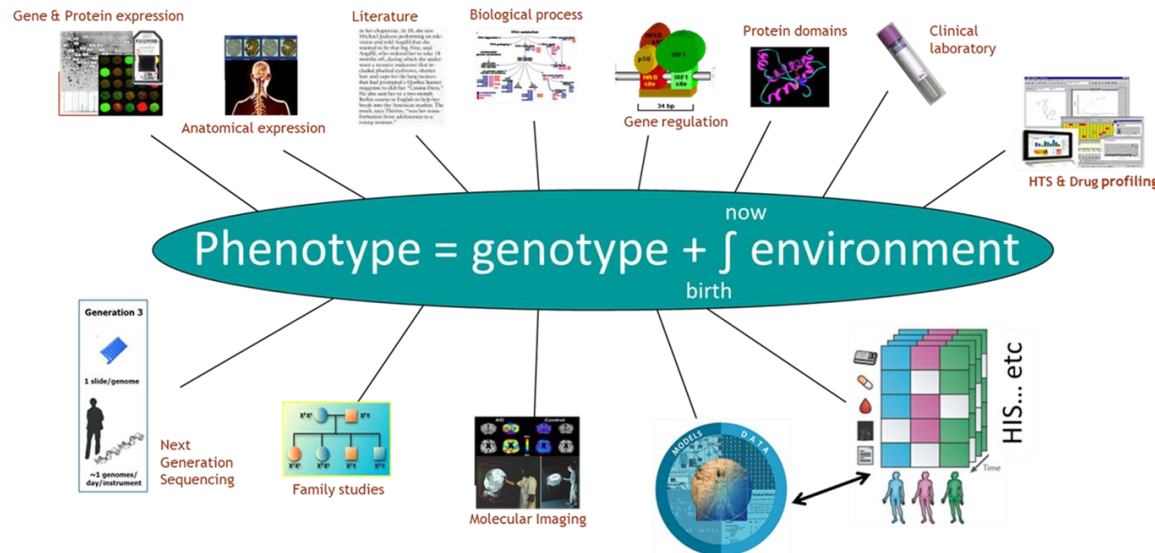
2015 ●

# Data usage in Healthcare

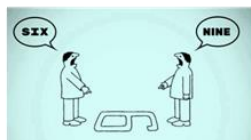
$Data^n = Value^\infty$  ...only if we make the data useable

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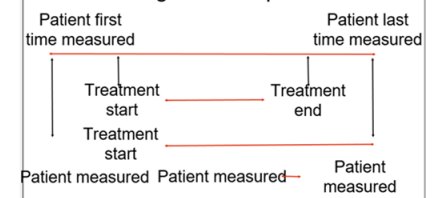
The goal: cross-cohort analyses  
The current situation



HOW STANDARDS PROLIFERATE:  
(SEE: A/C CHARGES, CHARACTER ENCODINGS, INSTANT MESSAGING, ETC.)



One easy measurement:  
weight loss of patient !



in Kg, Gramm, pounds, percentage ??

# Health Ecosystem







Data interoperability needs are increasing

# ITTM

Information Technology  
for Translational Medicine

## There are 7 types of orchestrators of digital health ecosystems – Leading examples globally

Who are the digital health ecosystem orchestrators and how do they capture value?

	1. Payor-led ecosystem							
	2. Provider-led ecosystem							
	3. HealthTech-led ecosystem							
	4. MedTech-led ecosystem							
	5. Pharmaco-led ecosystem							
	6. Pharmacy-led ecosystem							
	7. New entrant-led ecosystem							

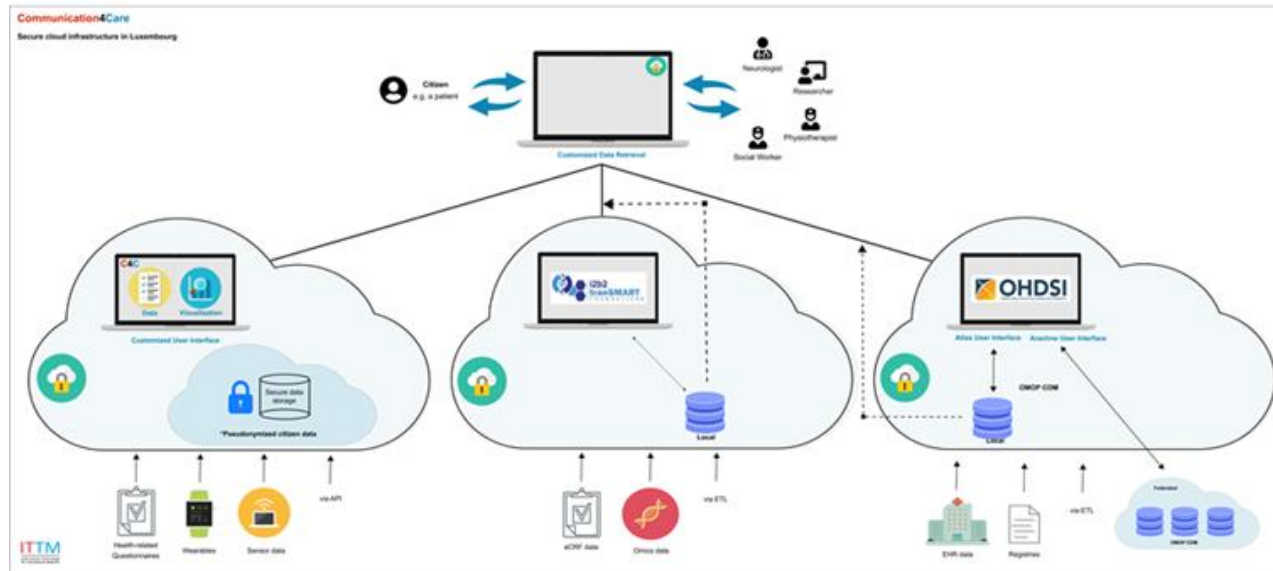
Non-healthcare players

## What will your role be in a healthcare ecosystem?



# Various Viewpoints of the same Data

## Some Thoughts



Data used in Clinical Studies and in Care (Clinic or Home) **are ,identical' (really?)**

- Consent vs User Agreement/Contract
- eCRF vs EHR or PHR (incl. lab results, medication, prescriptions, ...)
- PROMs and Wearables (medical & consumer grade)
- **episode or longitudinal; discrete or streaming data**
- **IMPORTANT: Data Protection, Privacy by Design; Data Processing Agreements, etc...**
- **AND... European Health Data Space**

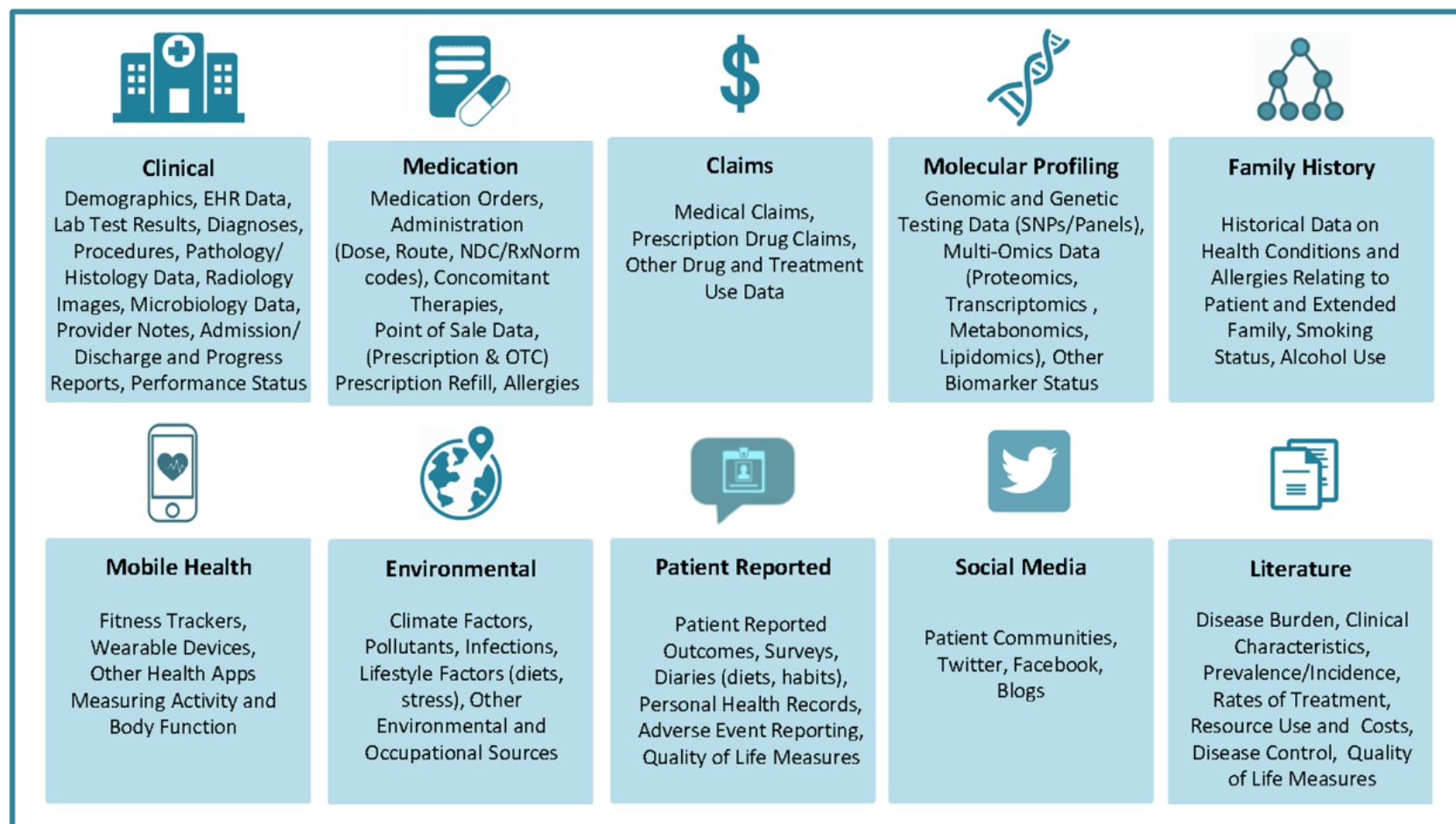


# Real-World Data (RWD)

Diverse in Type, Quality, Usefulness ?

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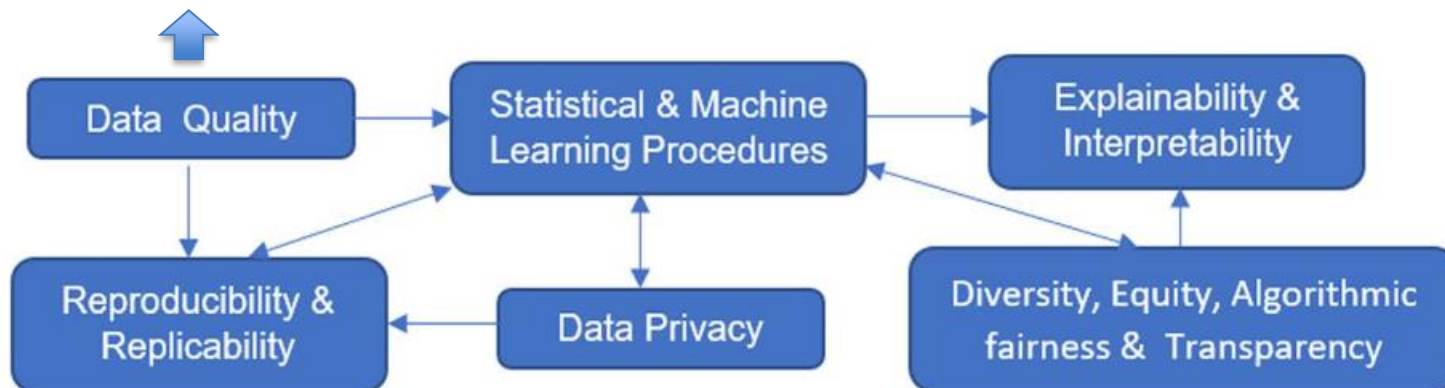
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**Fig. 1** RWD Types and Sources (source: Fig. 1 in [16] with written permission by Dr. Brandon Swift to use the figure)

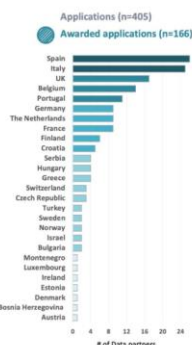
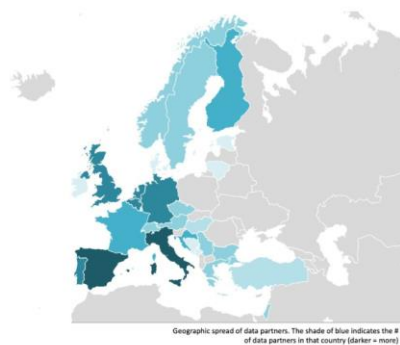
Liu and Demosthenes BMC Medical Research Methodology (2022) 22:287- <https://doi.org/10.1186/s12874-022-01768-6>

Completeness, Accuracy, Validity, Uniqueness, Consistency, Timeliness, Traceability, Clarity, Availability



**Becoming the  
trusted open science community  
built with standardised health data  
via a European federated network**

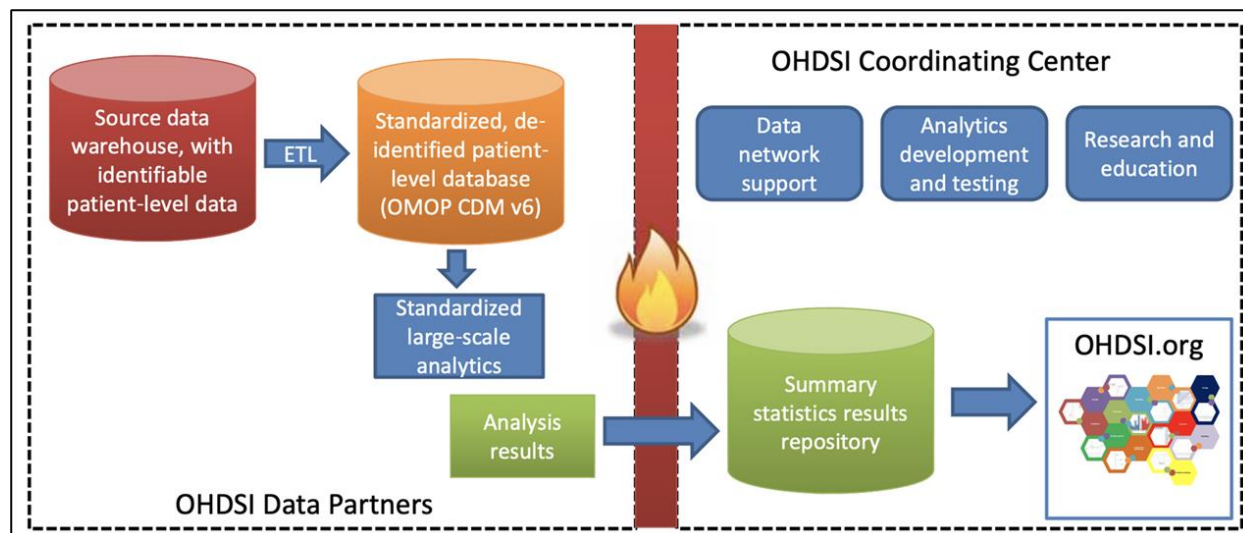




7 calls for data sources:  
166 Data Sources;

**EHDEN**  
2019  
CERTIFIED SME  
64 SMEs

Observational Health Data Sciences and Informatics  
Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM)

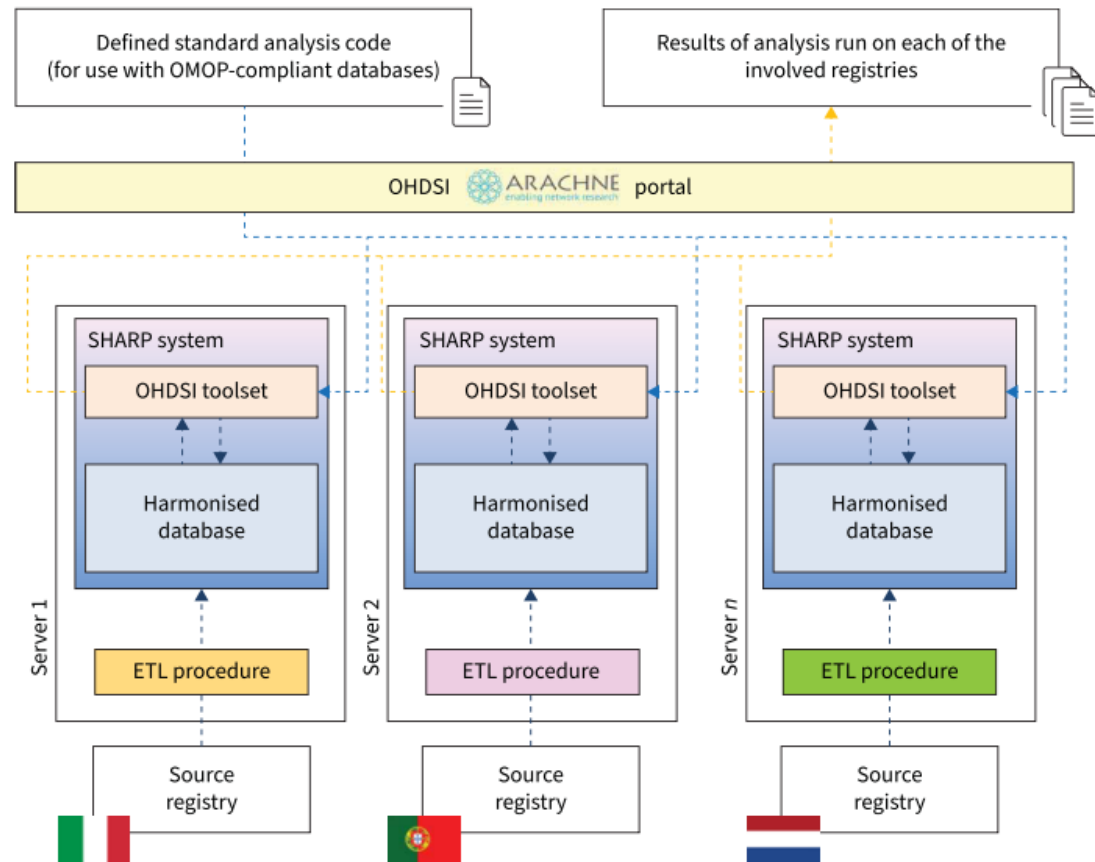
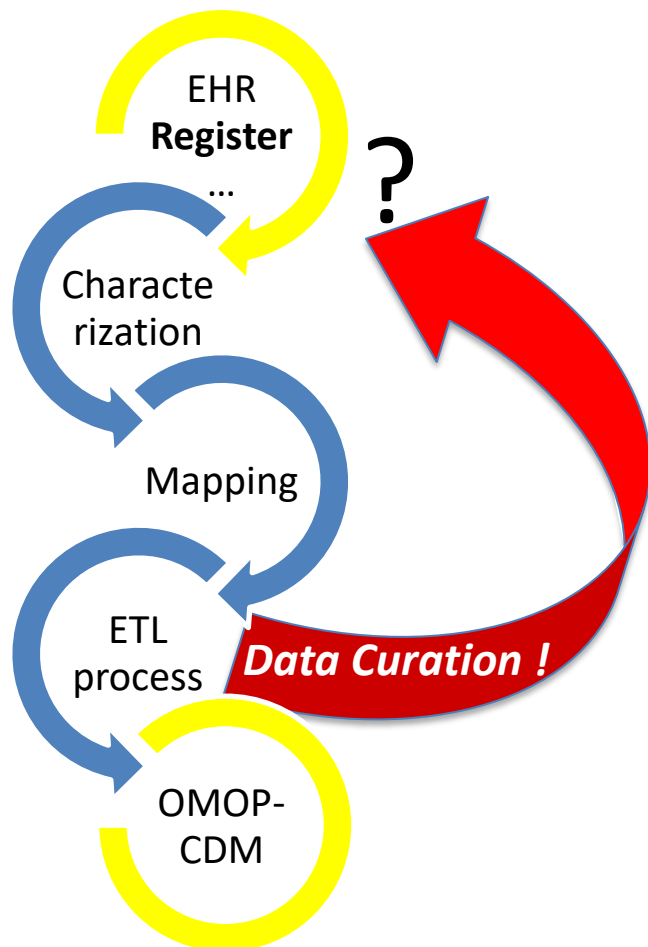


# Data Quality and CDM

Example ERS CRC-SHARP (severe asthma)

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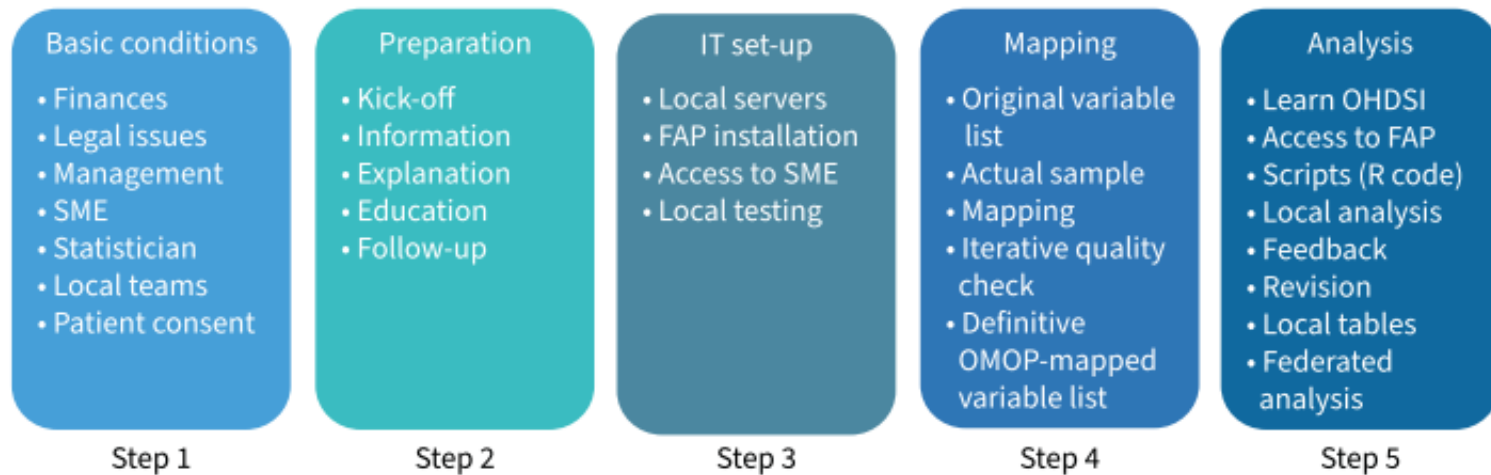
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Kroes JA, Bansal AT, Berret E, et al. Blueprint for harmonising unstandardised disease registries to allow federated data analysis: prepare for the future. ERJ Open Res 2022; 8: 001682022 [DOI: 10.1183/23120541.00168-2022].

# It's a process

Service Providers are needed on numerous levels !



**FIGURE 2** Schematic summary of steps to be taken for a successful harmonisation process of local nonstandardised disease registries to the Observational Health Data Sciences and Informatics (OHDSI)/ Observational Medical Outcomes Partnership (OMOP) Common Data Model for federated analyses. SME: small and medium-sized enterprise; IT: information technology; FAP: federated analysis platform.



## WHAT IS EU-PEARL?

Strategic alliance between the **public** and **private** sectors to:

Transform the way  
clinical trials  
are conducted

Place the **patient**  
at the center  
(co-designed by patients)

Improve and accelerate  
drug development  
processes

by developing a common framework  
for platform clinical trials/Integrated Research Platforms (IRPs)



"This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853966. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and CHILDREN'S TUMOR FOUNDATION, GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT NON PROFIT ORGANISATION, SPRINGWORKS THERAPEUTICS INC".

**This presentation reflects only the author's view and the JU is not responsible for any use that may be made of the information it contains.**

EU-PEARL consortium prepared a  
generic  
suite of master protocol templates

EU-PEARL consortium prepared a  
generic  
cross – functional platform trial  
study planning best practices tool

- 1) Master Protocol Template\*;
- 2) Interventions Specific Appendix\*;
- 3) Statistical Analysis Plan\*;
- 4) Data Monitoring Committee Charter;
- 5) Guidance on supplementary information to the CTR cover letter'. \*Based on TransCelerate Templates



THE PATIENTS



THE HOSPITAL  
HUBS



THE OPERATIONAL  
FRAMEWORK



THE DATA GOVERNANCE  
ECOSYSTEM



THE REGULATORY  
FRAMEWORK



# Next Steps

European OHDSI National Node Luxembourg

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Many European consortia are working with the OMOP-CDM and are enlarging the European data network – below a selection:



**PIONEER**



National Nodes from

- Germany
- Italy
- Greece
- Spain
- UK
- The Netherlands
- Luxembourg (submitted)



# Thank You – Grazie1000 – Merci



**ITTM** is a successful and innovative company with an excellent international customer network, a highly motivated and qualified team of managers and technical experts that creates profitable and scalable communication and data platforms and support its customers in **Making Data Actionable** for the rapidly expanding digital healthcare market.

## SECURE AND SCALABLE HEALTH DATA: MAKING REAL WORLD DATA ACTIONABLE.

Healthcare data is typically heterogeneous in nature and brings operational, technical, and methodological challenges. Wearables, sensors, smartphone apps, IT-based medical data management platforms profoundly change current healthcare models, with huge impact on all stakeholders and potential to increase patient's benefits and participation. Real-world data (RWD) also offers the possibility to derive novel insights on the use and performance of medicines in everyday clinical use, complementing rather than competing with evidence from randomized control trials.

There is increasing interest in the use of real-world data (RWD) to support clinical studies and regulatory decision making across the product life cycle. Key sources of RWD are electronic health records, claims data, prescription data, and patient registries. Increasingly incorporated into the definition is data from wearables, m-health apps, and environmental data including data on social status, education, and other lifestyle factors. There is a growing number of databases in healthcare organizations which contain this type of patient data. Still, to use this data optimally, we need to facilitate the collection of high-quality data and to foster standardized models and queries.

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