Secure and Scalable Health Data:

Making real world data actionable

3rd Annual Meeting of the de.NBI Industrial Forum
November 24th 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
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**

*(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

$$Data^n = Value^\infty \ldots \text{only if we make the data useable}$$

The goal: cross-cohort analyses
The current situation

Registry  Specialist case collection  Randomised controlled trial  Population-based study

One easy measurement: weight loss of patient!

<table>
<thead>
<tr>
<th>Patient first time measured</th>
<th>Patient last time measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment start</td>
<td>Treatment end</td>
</tr>
<tr>
<td>Patient measured</td>
<td>Patient measured</td>
</tr>
</tbody>
</table>

in Kg, Gram, pounds, percentage ??
Health Ecosystem

Data interoperability needs are increasing

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

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

What will your role be in a healthcare ecosystem?
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?

**Clinical**
- Demographics, EHR Data, Lab Test Results, Diagnoses, Procedures, Pathology/Histology Data, Radiology Images, Microbiology Data, Provider Notes, Admission/Discharge and Progress Reports, Performance Status

**Medication**
- Medication Orders, Administration (Dose, Route, NDC/RxNorm codes), Concomitant Therapies, Point of Sale Data, (Prescription & OTC) Prescription Refill, Allergies

**Claims**
- Medical Claims, Prescription Drug Claims, Other Drug and Treatment Use Data

**Molecular Profiling**
- Genomic and Genetic Testing Data (SNPs/ Panels), Multi-Omics Data (Proteomics, Transcriptomics, Metabonomics, Lipidomics), Other Biomarker Status

**Family History**
- Historical Data on Health Conditions and Allergies Relating to Patient and Extended Family, Smoking Status, Alcohol Use

**Mobile Health**
- Fitness Trackers, Wearable Devices, Other Health Apps Measuring Activity and Body Function

**Environmental**
- Climate Factors, Pollutants, Infections, Lifestyle Factors (diets, stress), Other Environmental and Occupational Sources

**Patient Reported**
- Patient Reported Outcomes, Surveys, Diaries (diets, habits), Personal Health Records, Adverse Event Reporting, Quality of Life Measures

**Social Media**
- Patient Communities, Twitter, Facebook, Blogs

**Literature**
- Disease Burden, Clinical Characteristics, Prevalence/Incidence, Rates of Treatment, Resource Use and Costs, Disease Control, Quality of Life Measures

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

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; 

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)

Data Curation!

EHR Register ...
Characte rization
Mapping
ETL process
OMOP-CDM

Defined standard analysis code (for use with OMOP-compliant databases)
Results of analysis run on each of the involved registries

OHDSI ARACHNE portal

SHARP system
OHDSI toolset
Harmonised database
ETL procedure
Source registry

SHARP system
OHDSI toolset
Harmonised database
ETL procedure
Source registry

SHARP system
OHDSI toolset
Harmonised database
ETL procedure
Source registry


© 2022 by IT for Translational Medicine
It’s a process
Service Providers are needed on numerous levels!

**Step 1**
- Basic conditions
  - Finances
  - Legal issues
  - Management
  - SME
  - Statistician
  - Local teams
  - Patient consent

**Step 2**
- Preparation
  - Kick-off
  - Information
  - Explanation
  - Education
  - Follow-up

**Step 3**
- IT set-up
  - Local servers
  - FAP installation
  - Access to SME
  - Local testing

**Step 4**
- Mapping
  - Original variable list
  - Actual sample
  - Mapping
  - Iterative quality check
  - Definitive OMOP-mapped variable list

**Step 5**
- Analysis
  - Learn OHDSI
  - Access to FAP
  - Scripts (R code)
  - Local analysis
  - Feedback
  - Revision
  - Local tables
  - Federated analysis

**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.

© 2022 by IT for Translational Medicine
EU-PEARL consortium prepared a generic suite of master protocol templates

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

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

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.

Dr. Andreas Kremer
Co-Founder and Managing Director
Information Technology for Translational Medicine (ITTM) S.A., Luxembourg