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ISPOR
Improving healthcare decisions

# Advancing Real-World Evidence Generation: Insights from Europe, the US, and China

The International Society for Pharmacoeconomics and Outcomes Research Europe Conference
Copenhagen, Denmark

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# Speakers

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# Part I – Advancing Patient-Centric Real-World Evidence

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# Patient-centric RWD challenges

- Following the launch of a newly approved product, there are high demands from key stakeholders (regulators, payers, clinicians, patients) for early patient-centric evidence (e.g., signs, symptoms, impacts, health-related quality of life [HRQL]) from the real-world clinical practice
- However, there exist challenges for patient-centric outcomes with conventional RWD (e.g., health insurance claims, registries, electronic health records and/or chart reviews)
  - Often not available
  - Not always accessible
  - Take a long time to reach a desired sample size
  - Often lack true baseline
  - May expect large attrition over time
  - Costly

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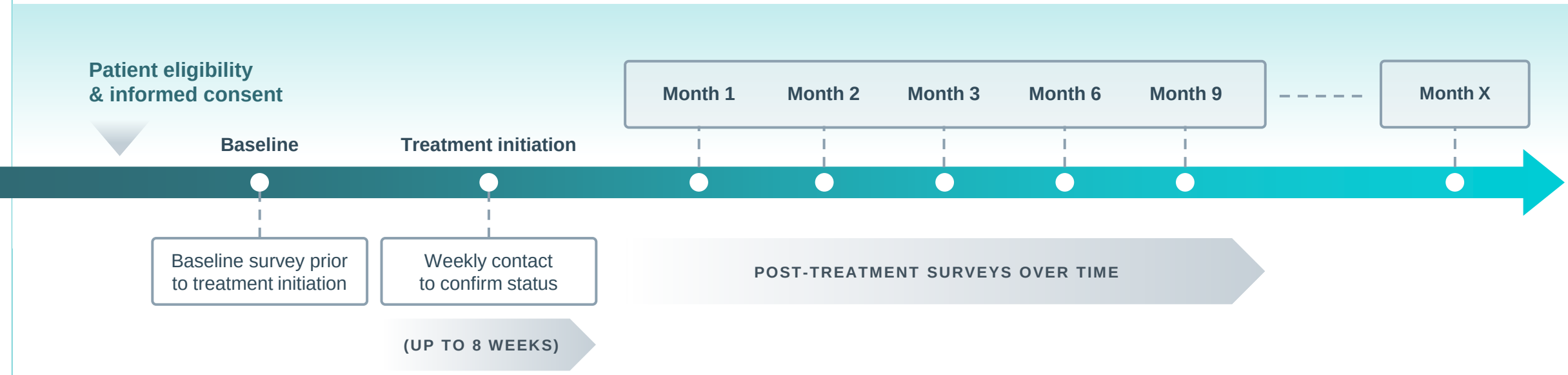
# Real-world PRO data solution: Longitudinal surveys of patients with recruitment through patient support programs (LEAP)

- In contemporary medicine, biopharmaceutical companies are inspired to generate patient-centric real-world evidence to address demands from stakeholders
- At the launch of a new medication, many companies offer patient support programs (PSPs) to help patients navigate the treatment journey
- PSPs offer an opportunity to recruit patients and follow them over time, allowing timely evidence generation



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# What does LEAP offer for patient-centric RWD generation?

- **Geographic/practice representation** (e.g., not limited to centers of excellence)
- **Capturing true baseline** (i.e., patient status prior to treatment initiation)
- **Timely real-world patient-centric data** for an early view of patient experiences before vs. after a new treatment starts
- **High retention rate** and **long-term follow up**
- **Sustainable and cost-effective data solution** directly from patients with long-term follow up data (vs. registry)
- **Reflective of patient profiles** in clinical practice
- **Reflective of key characteristics** in signs, symptoms, function, impacts on patients (e.g., HRQL, productivity)
- **Opportunity to link** to other data sources to create integrated and comprehensive RWD

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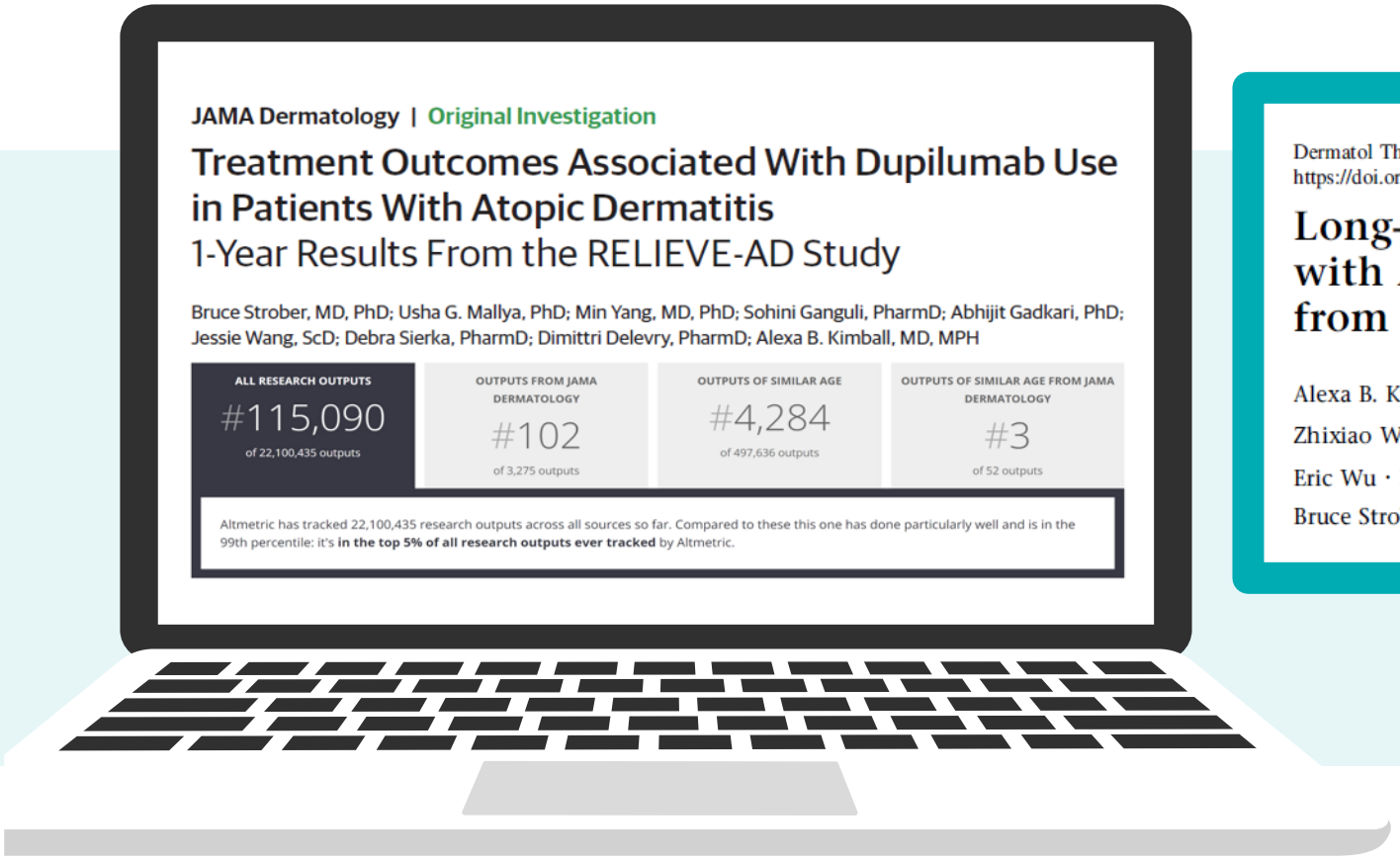
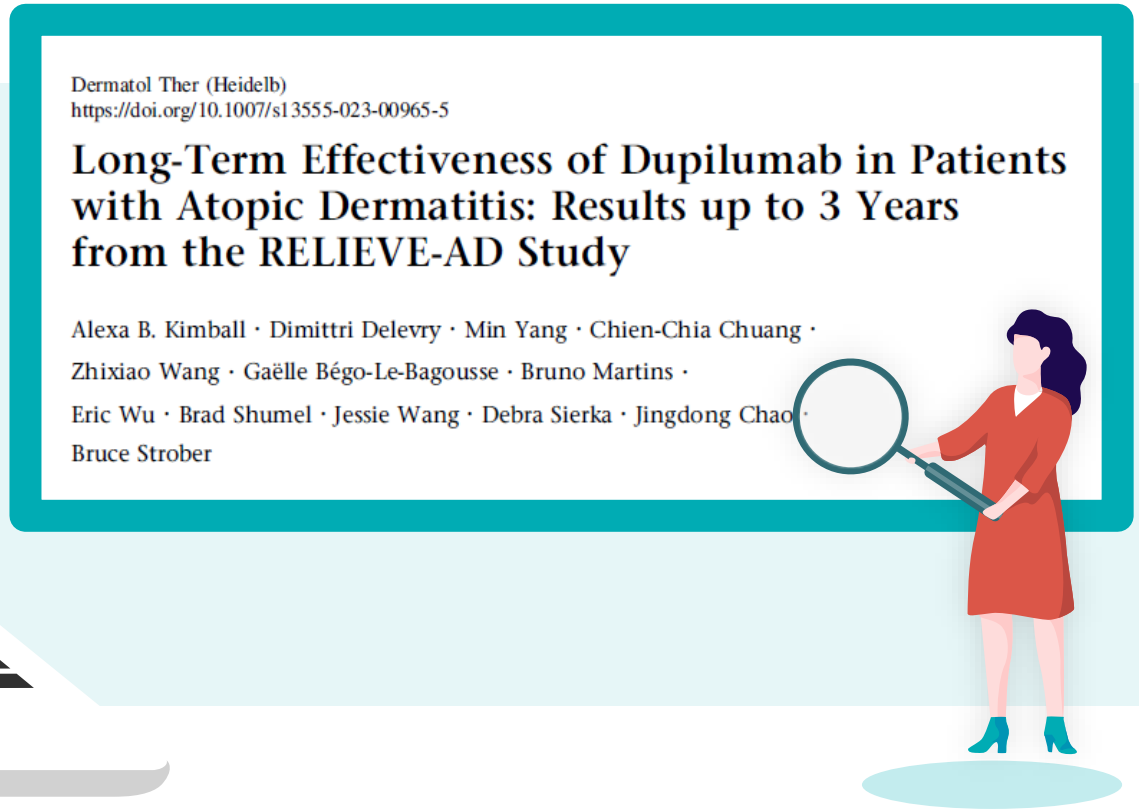
# First LEAP project, highly recognized by the research/medical community with Year 1 results in *JAMA Dermatology*, Year 3 results recently published



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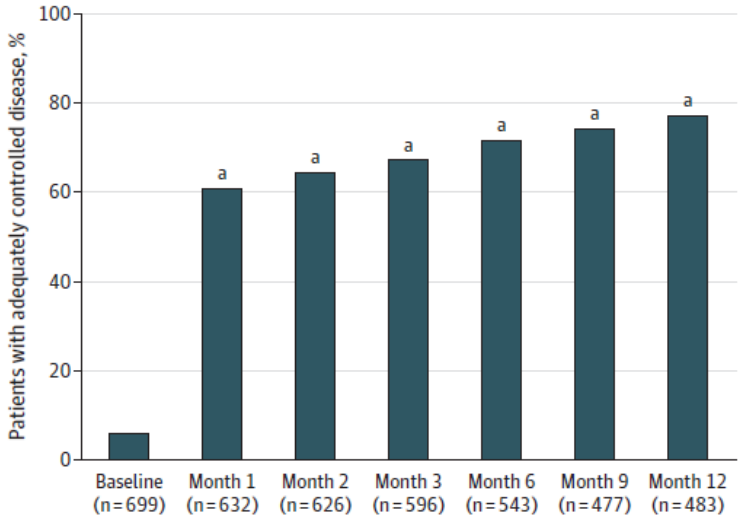
# Selected RELIEVE-AD Year 1 Findings

Focused on signs, symptoms, disease-specific impacts, HRQL, treatment satisfaction, work productivity and activity

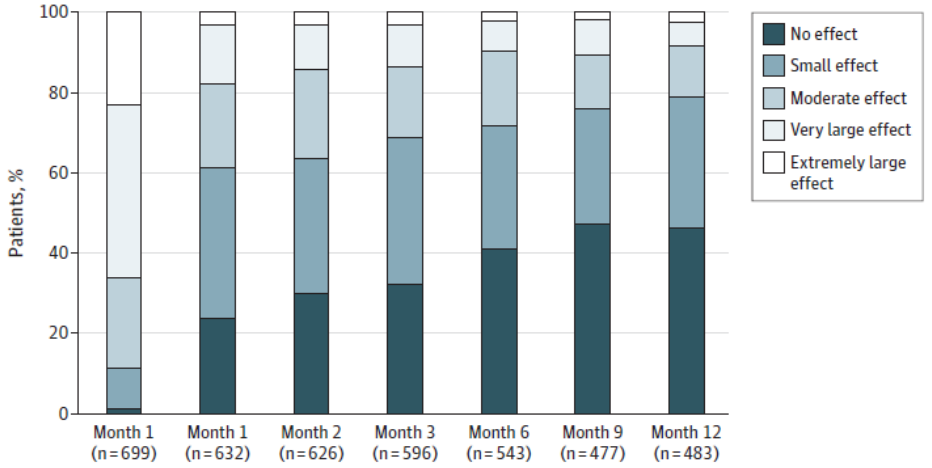
**Figure 1. Disease Control Assessed Using the Patient-Reported Atopic Dermatitis Control Tool (ADCT)**




Adequate disease control reflects a total ADCT score lower than 7.

[a] $P < .001$ vs baseline.

B Effect of atopic dermatitis on patients' lives based on DLQI




| PMM range, % | | | | | | |
|---|---|---|---|---|---|---|
| Extremely large effect | 3.0-4.6 | 2.9-5.5 | 2.7-7.3 | 1.7-6.1 | 1.3-7.8 | 1.7-12.1 |
| Very large effect | 13.9-17.7 | 10.3-14.0 | 9.1-15.4 | 6.1-20.0 | 6.5-27.5 | 4.4-20.8 |
| Moderate effect | 20.2-21.3 | 21.2-22.2 | 16.5-17.8 | 15.6-18.6 | 10.1-13.2 | 9.8-12.8 |
| Small effect | 34.7-37.3 | 31.8-33.9 | 32.8-36.4 | 26.1-30.6 | 22.0-28.7 | 12.3-32.7 |
| No effect | 21.6-27.2 | 26.8-33.2 | 27.6-38.3 | 32.1-49.9 | 32.4-60.0 | 32.0-58.6 |

A, Percentage of patients with clinically meaningful change (≥4 points) on the DLQI.[30] B, Effect of atopic dermatitis on patients' lives based on DLQI (bands of 0-1 = no effect, 2-5 = small effect, 6-10 = moderate effect, 11-20 = very large effect, and 21-30 = extremely large effect).[29]

*Strober B, Mallya UG, Yang M, Ganguli S, Gadkari A, Wang J, Sierka D, Delevry D, Kimball AB. Treatment Outcomes Associated with Dupilumab in Patients with Atopic Dermatitis: 1-Year Results From the RELIEVE-AD Study. JAMA Dermatology 2022;158:142-150*

# Selected RELIEVE-AD Year 3 Findings

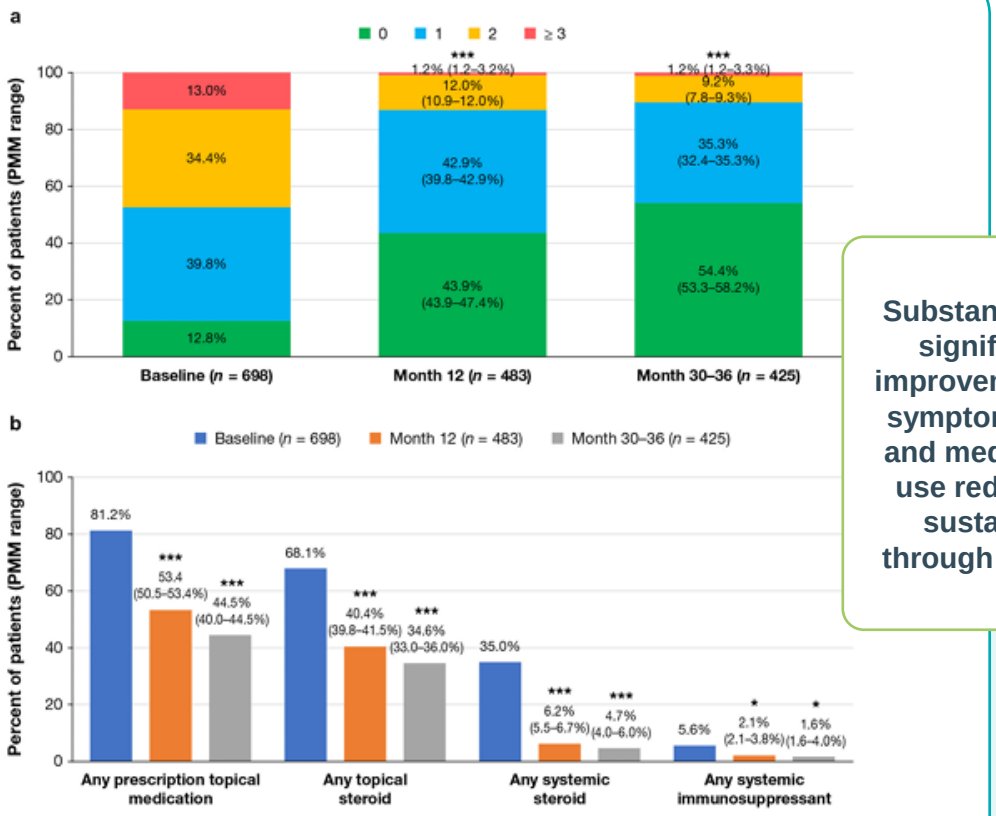



**Fig. 1** Medications for AD used in the previous 4 weeks other than dupilumab. **a** Number of concomitant medications. **b** Class of concomitant medications. *AD* atopic dermatitis, *PMM* pattern-mixture model. $^{*}P < 0.05$ and $^{***}P < 0.001$ vs. baseline

**Substantial and significant improvements in symptom (itch) and medication use reduction sustained through 3 years**

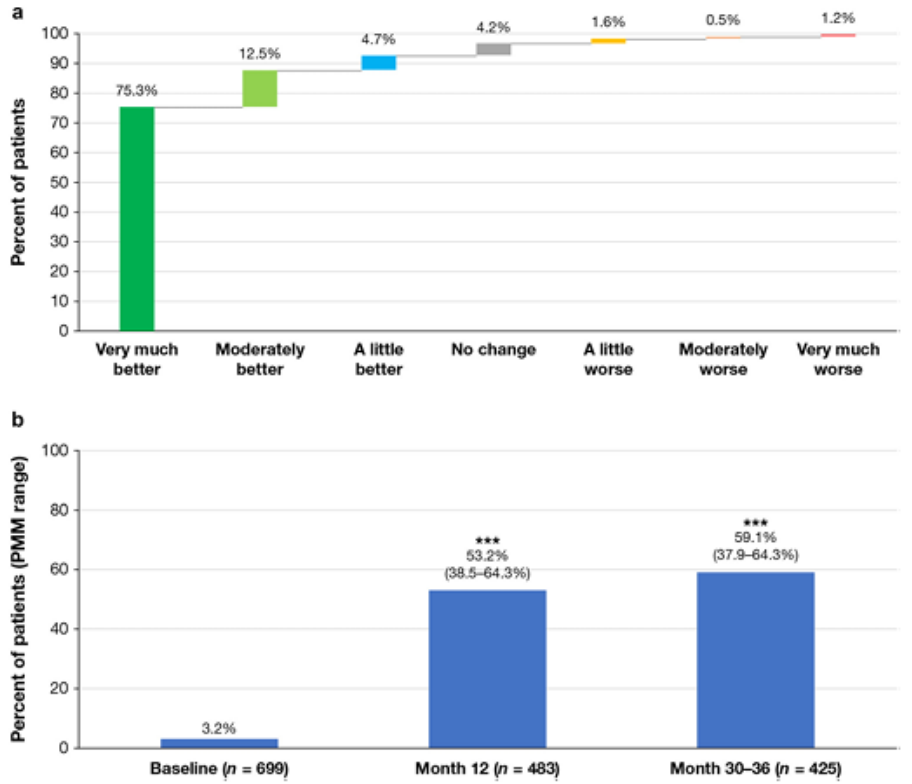



**Fig. 2** Itch symptoms. **a** Global change in itch at the 30–36-month recontact assessment relative to itch before initiation of dupilumab treatment. **b** Patients with no days of intense episodes of itching over the past week based on item 2 of the Atopic Dermatitis Disease Control Tool. *PMM* pattern-mixture model. $^{***}P < 0.001$ vs. baseline

*Kimball AB, Delevry D, Yang M, Chuang CC, Wang Z, Bégo-Le-Bagousse G, Martins B, Wu E, Shumel B, Wang J, Sierka D, Chao J, Strober B. Long-Term Effectiveness of Dupilumab in Patients with Atopic Dermatitis: Results up to 3 Years from the RELIEVE-AD Study. Dermatol Ther (Heidelb). 2023 Sep;13(9):2107-2120. doi: 10.1007/s13555-023-00965-5. Epub 2023 Aug 8. PMID: 37552431; PMCID: PMC10442302.*

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# LEAP solution crosses various therapeutic areas with multi-year follow up

## Therapeutic Areas

Cardiology

Dermatology

Gastroenterology

Hematology

Neuromuscular Disorders

Rare Genetic Disorders

Pediatric Diseases

Respiratory Conditions

## Follow-up Period

**1 – 10 years**

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# Continue advancing the LEAP data solution

## Linking to external data through tokenization

- With consent from LEAP enrollees, essential personal identifiable information (PII) is collected from participants.
- Through a de-identification engine, encrypted patient tokens can be generated consistently for any dataset when the underlying PII is the same.
- Matching tokens can be used to link survey responses from a LEAP study to other data sources (e.g., health insurance claims, EHR) without exposing the PII of that patient.

## Incorporating movement data using medical device

- Some diseases have a direct impact on patients' physical activity, functional abilities, or sleep.
- Upon consent from LEAP enrollees, digital health monitoring tools such as watch devices are mailed to study participants to capture movement data beyond PROs.

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# LEAP evolvement and key design considerations

- Real-world patient-centric data are playing an increasingly important role in policymaking and treatment decisions
- Since its inception, the LEAP solution has evolved from focusing on patient-reported outcomes only to be a hub connecting and incorporating multiple data sources to generate the integrated and comprehensive RWE
- LEAP has a complex design. Multifaceted expertise and experiences in working with stakeholders of diverse backgrounds and varying functions are crucial to its successful implementation
  - In-depth knowledge of the medical condition and related treatments to ensure a strategic planning
  - Expertise in providing coherent coordination, alignment, and guidance across internal and external stakeholders
  - Thorough design considerations for developing surveys and patient-facing materials, reflecting short- and long-term strategies
  - Ample anticipation of potential roadblocks with both extensive experiences and creative minds for solutions

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# Other considerations

**Other patient channels**

Other than manufacturers' programs such as patient support programs, LEAP opens the door for recruitment through other patient channels (e.g., patient advocacy groups) for study enrollment and longitudinal follow-up (e.g., an in-depth understanding of natural history of diseases, particularly for rare diseases, from a patient's perspective)

**Caregiver engagement**

Some disorders affect paediatric patients or older adults, and some cause disability or mental health problems. Caregivers are a critical component in their life. Caregiver in a LEAP study can serve as a proxy and/or share disease and treatment impacts from a caregiver's perspective

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# Part II – Collaborative RWD Initiatives in China

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# Embracing real-world data in health care

## RWE plays an important role in market access in China

### Real-world insights

- Representativeness and generalizability
- High velocity, granularity, and diversity
- Exerting a profound impact on decision making

### Statistical power

- Substantial sample sizes for research questions
- Long-term insights into continuous disease process and treatment outcomes

### Hypothesis-free process

- Fact-based parameters and data-driven findings
- Broad scope facilitating various research needs

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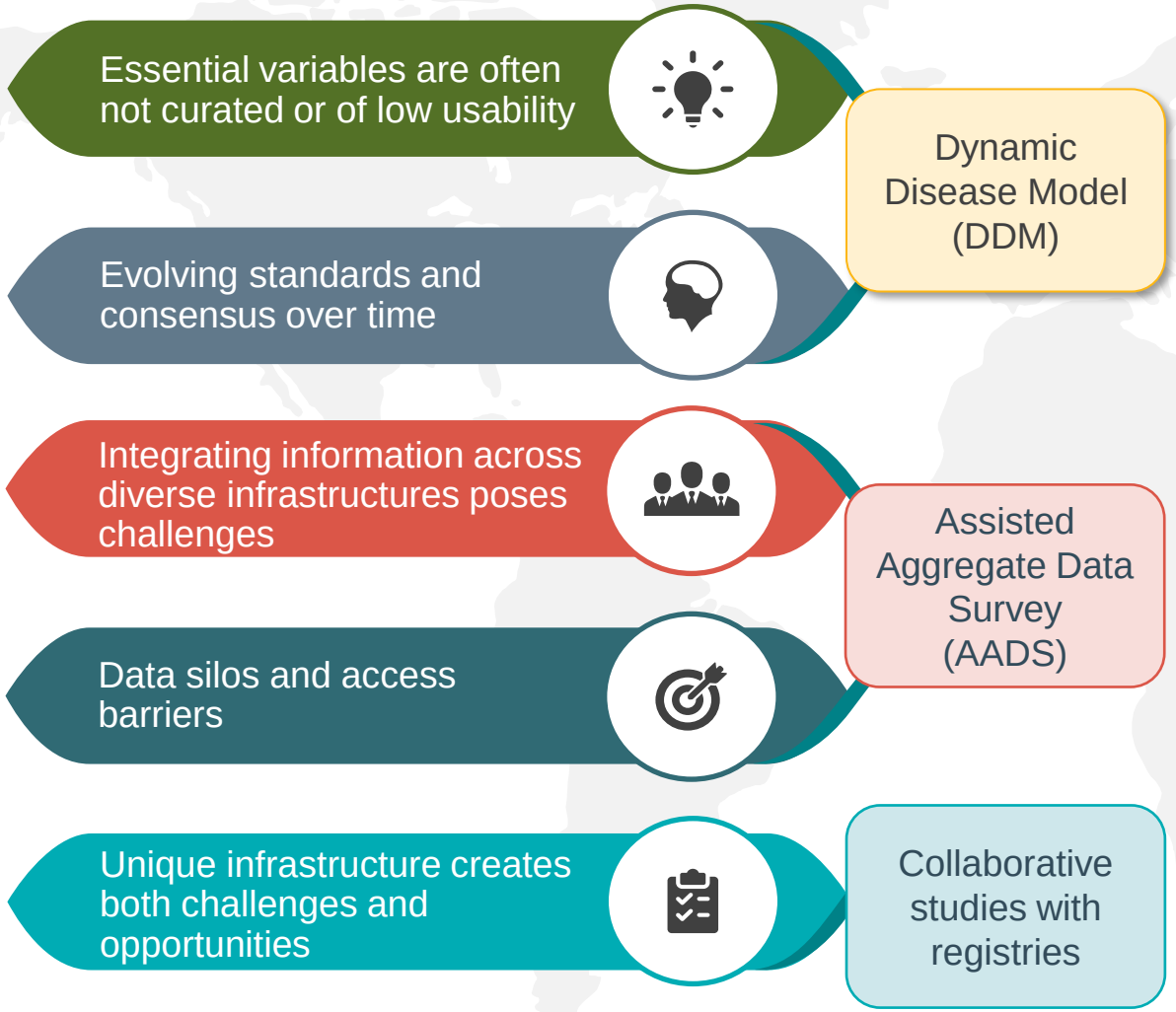
# Innovation and nimbleness are essential for addressing data gaps




DDM utilizes validated clinical algorithms that are grounded in factual clinical data, to provide essential insights for reconstructing clinical pathways.

– Facilitates adjustments and recalculations to align with evolving clinical standards

AADS implemented a system-based aggregate data approach to facilitate federated learning across multiple centers, offering a swift turnaround time.

– Strikes a balance between addressing immediate requirements and achieving long-term objectives

China's data initiatives leverage its substantial population base and integrate patient follow-up protocols into routine clinical management.

– Create significant opportunities for *ad hoc* data collection and patient-centric studies

# National Longitudinal Cohort of Hematological Diseases in China (NICHE)

Dynamic Disease Model to mechanize information integration and maximize research value

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# National Longitudinal Cohort of Hematological Diseases in China (NICHE)

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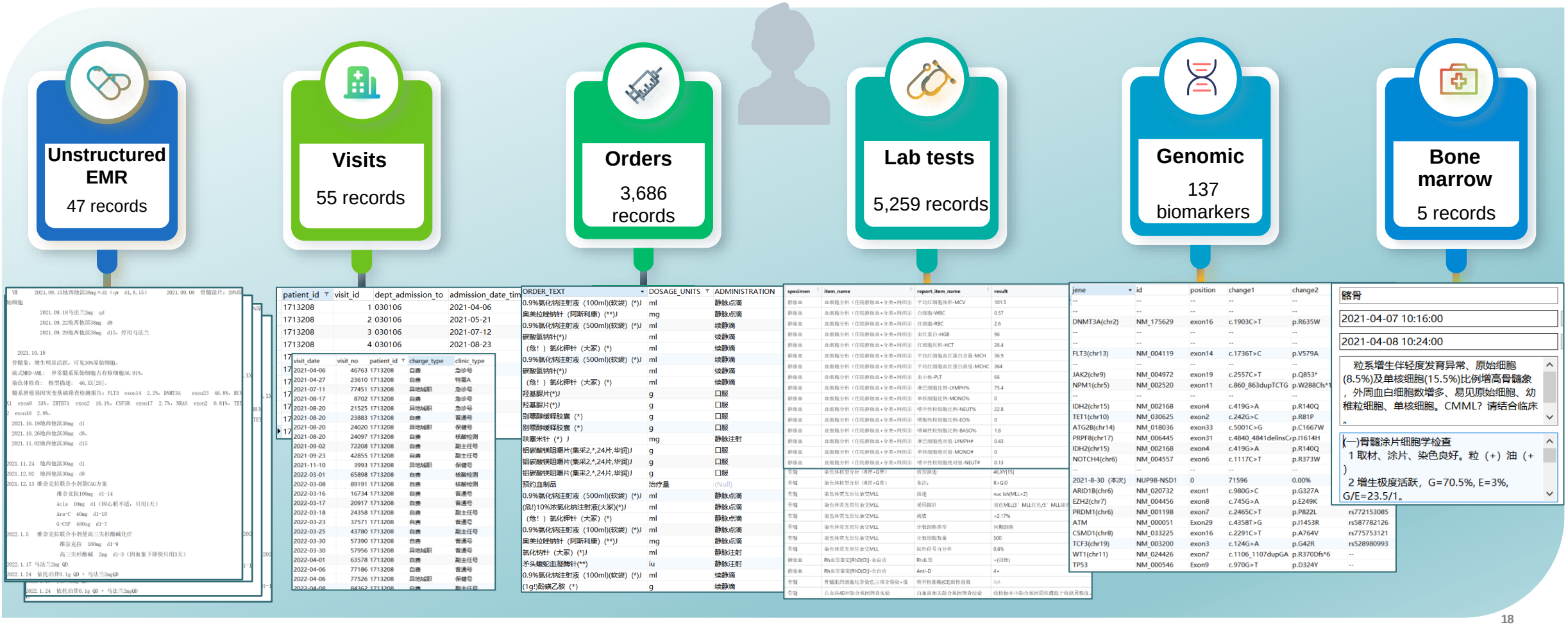
# How extensive is the volume of data linked to an individual patient?

## Illustration with simulated data



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# These extensive data fall short in addressing important questions

## Barriers to building high-quality hematology RWD

1

### Treatment response

**Inconsistent and evolving definition**

- Inconsistent response definitions, depending on practice, e.g., various definitions of refractory AML across countries
- Evolving clinical guidelines and gold standards with the emerging knowledge of disease and treatments

2

### Line of therapy

**Incomplete and unstructured recording**

- Line of therapy is often incomplete/missing
- A small proportion of records can be recovered from unstructured EMR, requiring extensive data extraction, pre-processing, and validation efforts

3

### Risk stratification

**Heterogeneous grouping and inconsistent standards**

- European LeukemiaNet (ELN) risk stratification is updated frequently, but its adaptation into clinical practice has a latency period due to its complexity and data requirements
- Some ELN risk factors are not routinely measured, especially in non-top-tier centers

***Abbreviation**: AML, acute myeloid leukemia; EMR, electronic medical record; RWD, real-world data*

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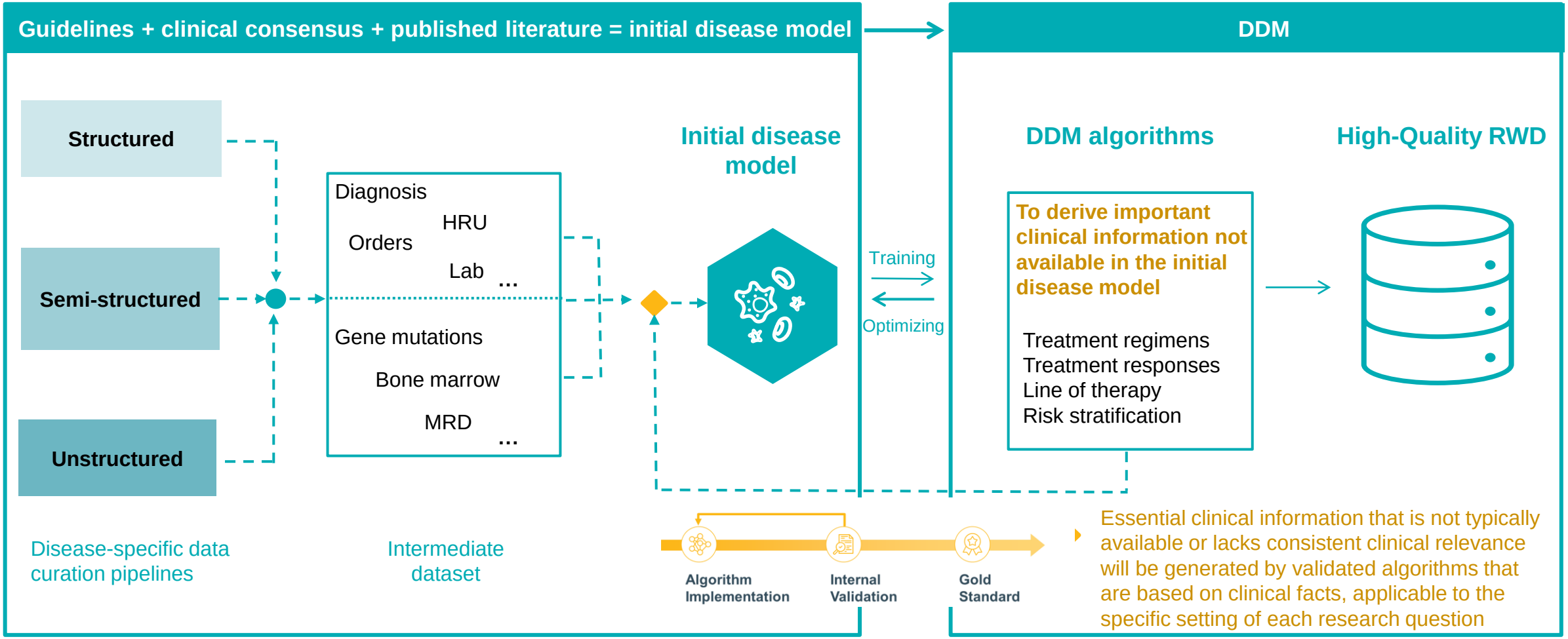
# A dynamic disease model (DDM) was developed to address data gaps

## A nimble architecture to contextualize and maximize RWD value




**Abbreviations**: AI: artificial intelligence; HRU, health resource utilization; MRD, minimal residual disease

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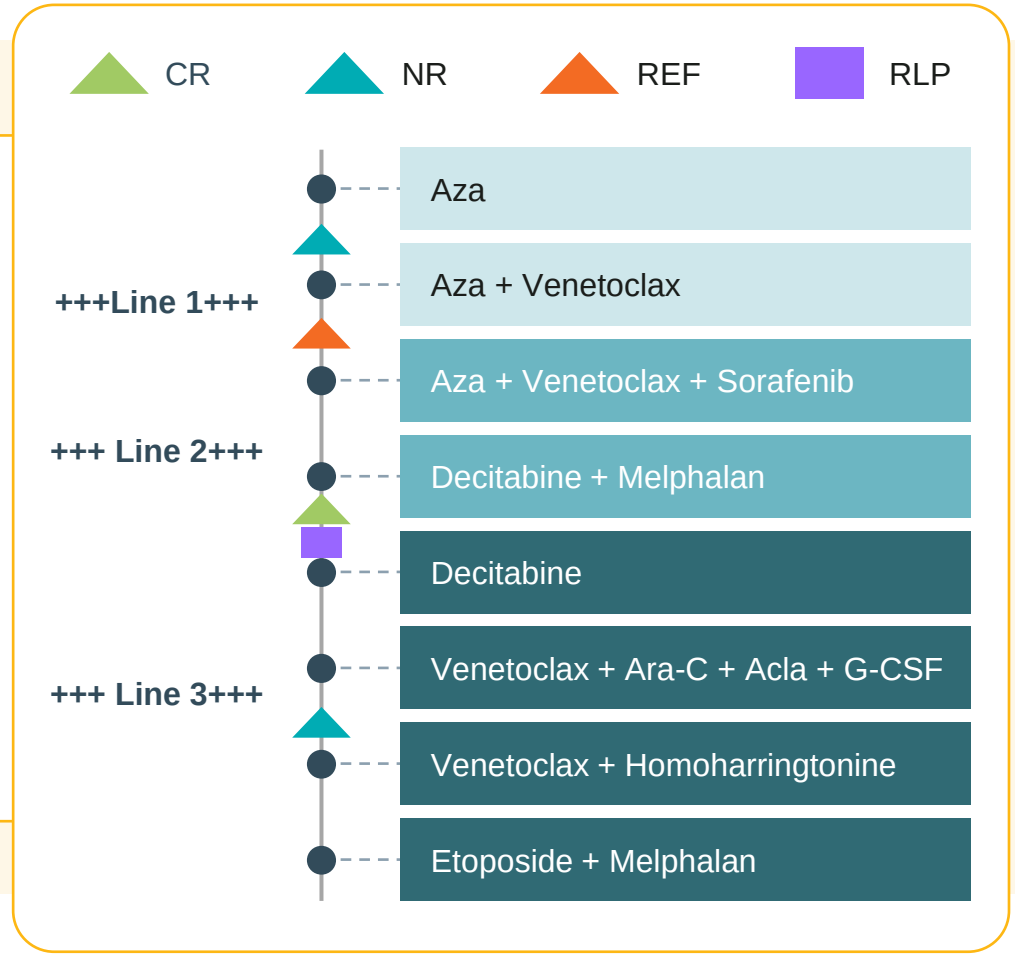
# DDM leverages clinical facts and validated algorithms

## Illustration with simulated data

### Raw records

- 55 — Inpatient and outpatient visits
- 3,686 — Prescriptions and orders
- 5,259 — Lab tests

- 5 — Clinical outcomes
- 3 — Lines of treatment
- 8 — Multi-agent regimens




***Abbreviations***: *CR, complete remission; NR, no remission; REF, refractory; RLP, relapse*

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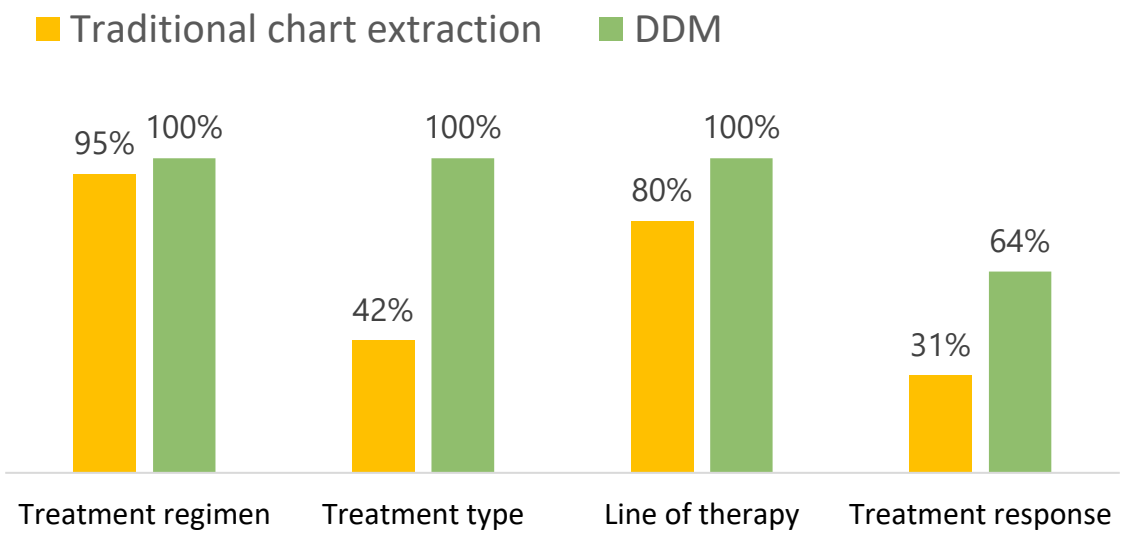
# Does the performance of DDM surpass that of traditional chart extraction?




## Data completeness

Line of therapy
Treatment response

**98.5%**

## An ongoing accuracy validation study

Heterogeneous data infrastructures across settings can lead to incomplete outpatient treatment records. Multi-system crosstalk is warranted to complete **treatment regimens by line.**

The recording of **treatment response** assessments in charts are determined by the timing of ward round documentations rather than the actual assessment schedules.

**Treatment types** such as induction, consolidation, and maintenance are not mandatory EMR fields, while the temporal sequence and dosage of treatments are recorded.

One limitation of DDM is its inability to address irretrievable data where patients have not undergone necessary examinations for response evaluation, leading to "**hard missingness**."

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ARC
AML REAL WORLD EVIDENCE INITIATIVE

# Global Acute Myeloid Leukemia Real-world Evidence (ARC) initiative

## A pioneering international longitudinal multi-center study engaging top-tier academic sites

**US, 12**

Memorial Sloan Kettering Cancer Center
MD Anderson Cancer Center
Weill Cornell Medicine
Georgetown University
UW Health
The University of Alabama at Birmingham
Moffitt Cancer Center
The University of North Carolina at Chapel Hill
Cancer Center
Dana-Farber Cancer Institute
Medical College of Wisconsin
Duke Health

**Israel, 4**

Rabin Medical Center Beilinson • Hasharon
Rambam Health Care Campus
Hadassah University Medical Center
Tel-Aviv Sourasky Medical Center
Medical Excellence and Compassionate Care

**China, 3**

中国医学科学院 北京协和医学院 血液病医院 血液学研究所
河南省肿瘤医院 郑州大学附属肿瘤医院
山东大学齐鲁医院 Qilu Hospital of Shandong University

**Canada, 1**

Sunnybrook Health Sciences Centre

**Other countries, 5**

**300+** patients from **3** centers since Dec. 2022
**94%** with genetic mutation tested
**98%** with bone marrow results

**500+** patients from **22** centers

# Assisted Aggregate Data Survey

Innovative solutions to generate timely and reliable RWE

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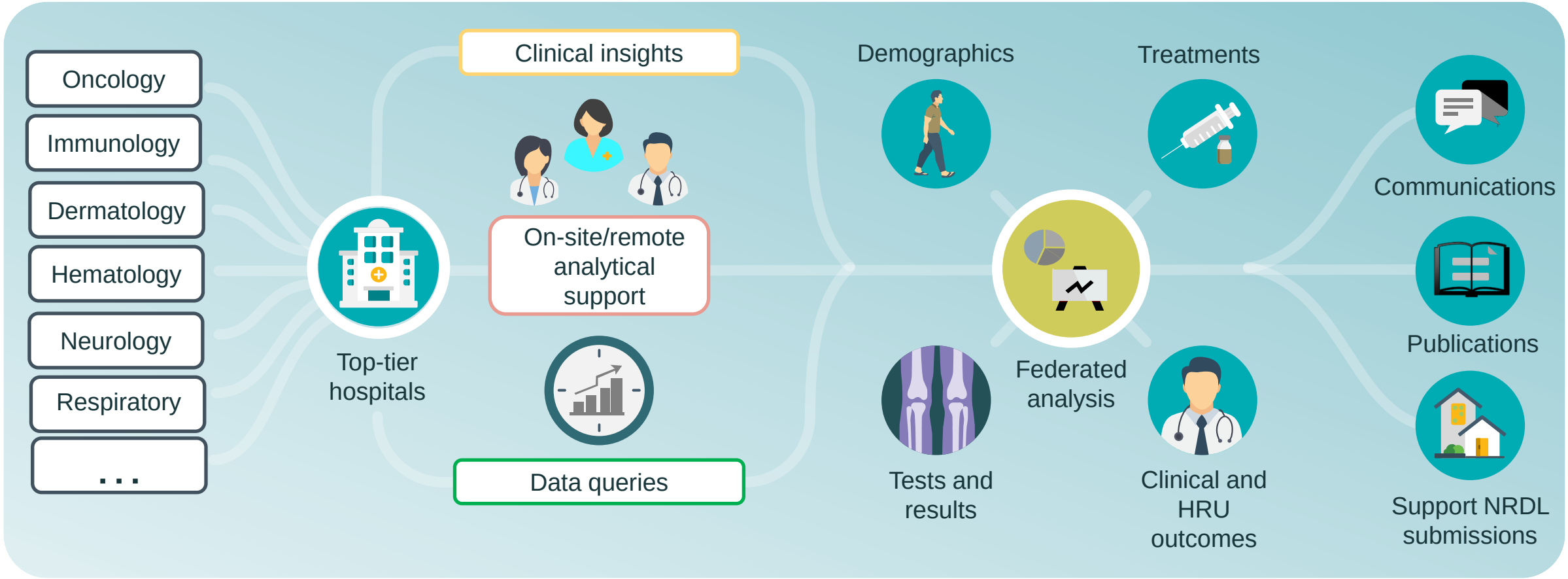
# AADS is a unique method combining data-driven inputs and clinical insights




**Disease areas** | **Methodology** | **Data domains** | **Applications**

# Huashu healthcare cOnnect PanEl (HOPE) offers a large network including 300+ tertiary grade-A hospitals

## An extensive physician and hospital network with established technology infrastructure to support AADS

### Selected hospitals that we have partnered with in AADS studies:

- Ruijin Hospital
- Beijing Hospital
- Tongji Hospital
- Peking University First Hospital
- The First Affiliated Hospital of Guangzhou Medical University
- Institute of Hematology/Blood Diseases Hospital
- West China Hospital of Sichuan University
- Sun Yat-sen University Cancer Center
- Beijing Chest Hospital
- Xuanwu Hospital, Capital Medical University
- Jiangsu Cancer Hospital
- Harbin Medical University Cancer Hospital
- Tianjin Medical University Cancer Hospital
- Hunan Cancer Hospital

- Zhongshan Hospital
- The Second Hospital of Dalian Medical University
- The First Affiliated Hospital of Wenzhou Medical University
- Henan Provincial People's Hospital
- Tianjin Medical University General Hospital
- Shengjing Hospital of China Medical University
- The First Affiliated Hospital of China Medical University
- Zhejiang Hospital
- Anyang District Hospital
- Dezhou Hospital
- The Second Hospital of Hebei Medical University
- Zhongshan City People's Hospital
- Tangdu Hospital
- Shanghai Pulmonary Hospital

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# AADS generated timely and reliable RWE to support market access of a rare disease drug in China

## A case study of eosinophilic granulomatosis with polyangiitis (EGPA)

**Background**

- EGPA is a rare condition associated with substantial disease burden
- Evidence based on local data is warranted to support regulatory and formulary milestones
- Generating RWD for rare conditions is typically resource intensive and time consuming
  - Only 7 months to close the RWD gap
  - IRB and HGRAC approvals take 6-8 months limiting feasibility of primary data generation, such as multi-center analyses

**Key considerations**

- Health care resource allocation is centralized in China, especially for rare conditions, and the number of physicians highly experienced in EGPA management is limited
- Early KOL engagement is critical in market access (e.g., reimbursement, hospital inventory listing)
- An efficient strategy should also serve as a feasibility assessment to facilitate future RWE initiatives and formulate research questions

**Solutions**

The aggregate RWE study aims to understand the disease burden due to EGPA in China, based on top tertiary hospitals' experience

Reference: Clinical Manifestations and Health Care Resource Utilization of Eosinophilic Granulomatosis with Polyangiitis (EGPA) in China: A Cross-Sectional Multi-Center Physician Survey Study (2022), Value in Health 25(7):S392 DOI:10.1016/j.jval.2022.04.543

Abbreviations: HGRAC, Human Genetic Resource Administration of China; IRB, institutional review board

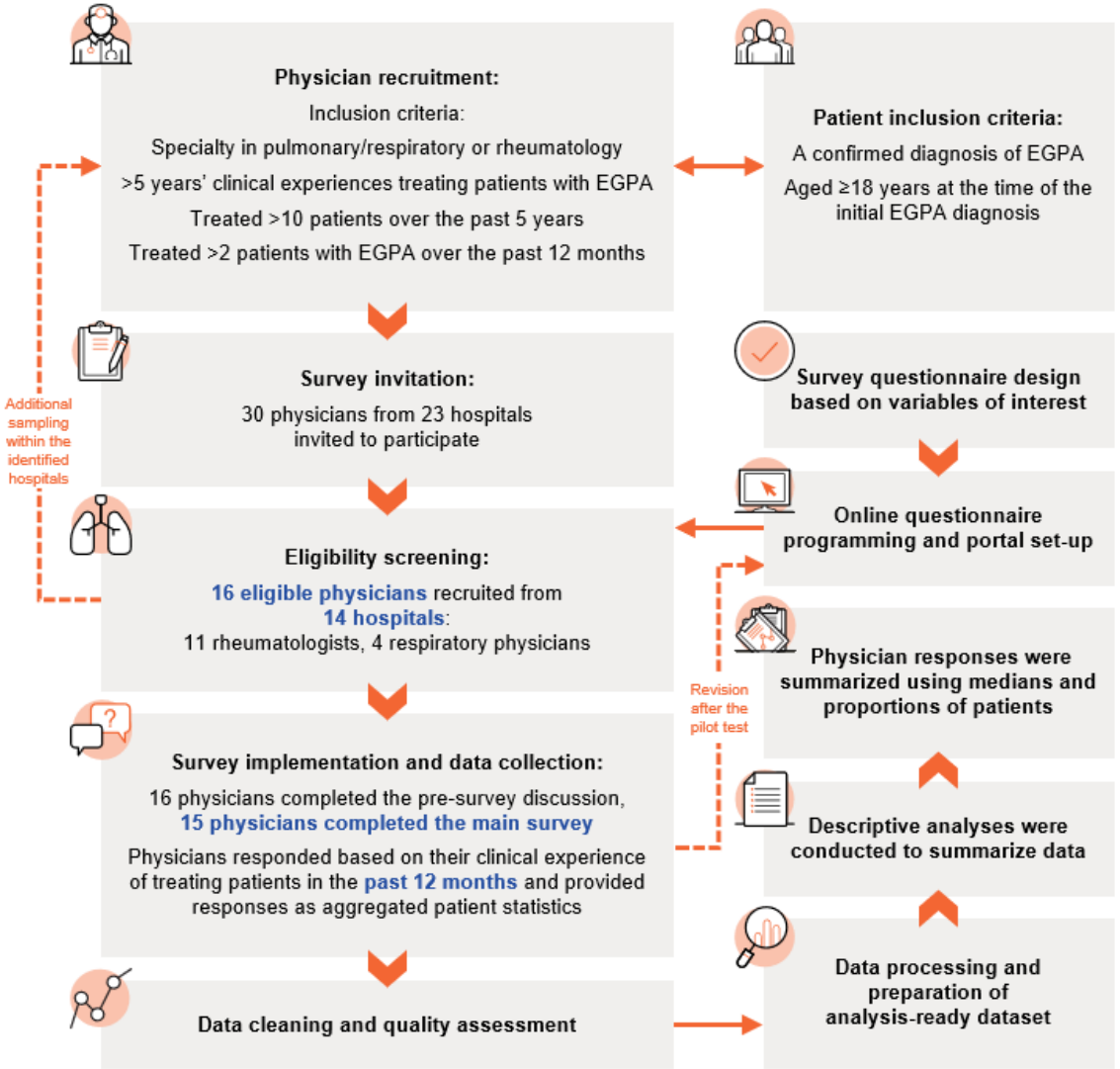



**Figure 1. Patient demographics and clinical characteristics (N=243*)**

**Demographics:**

**Male, %, median (range)**
46.0 (20.0, 75.0)

**Age at EGPA diagnosis, years, median (range)**
45.3 (35.0, 60.0)

**Clinical characteristics:**

**Time from asthma diagnosis to EGPA diagnosis, years, median (range)**
4.4 (0.5, 15.0)

**Blood eosinophil count test at EGPA diagnosis, %, median (range)**
100.0 (71.4, 100.0)

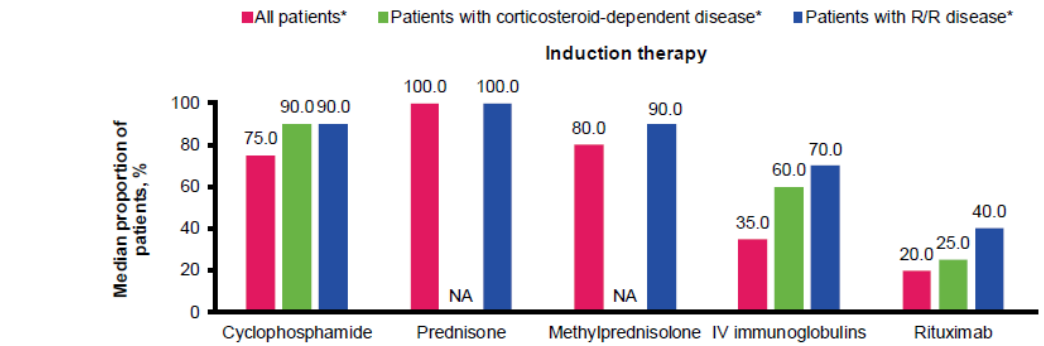
**Positive ANCA at EGPA diagnosis, %, median (range)**
50.0 (0.0, 100.0)

*Aggregated patient statistics were reported by physicians, n=15.

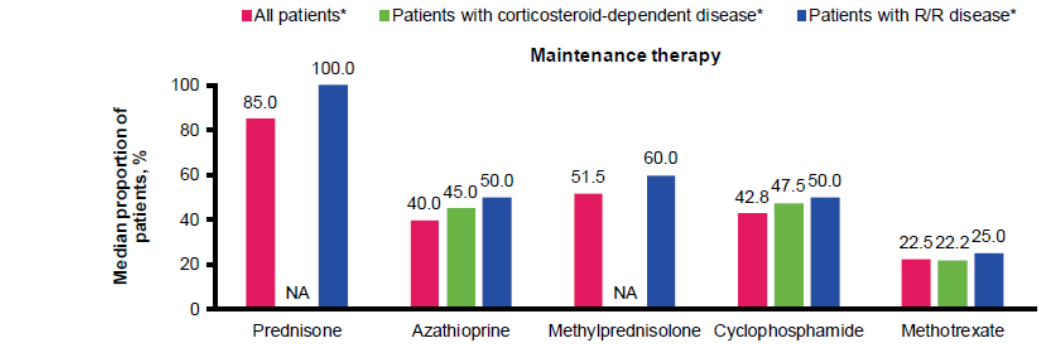
- In total, 44% of physicians had been in practice for 11–20 years and 56% for >20 years (N=16)

Abbreviations: AADS, assisted aggregate data summary; RWE, real-world evidence.

## Figure 2. Prednisone, methylprednisolone, and cyclophosphamide were the most used treatments for EGPA remission induction and maintenance for all patients



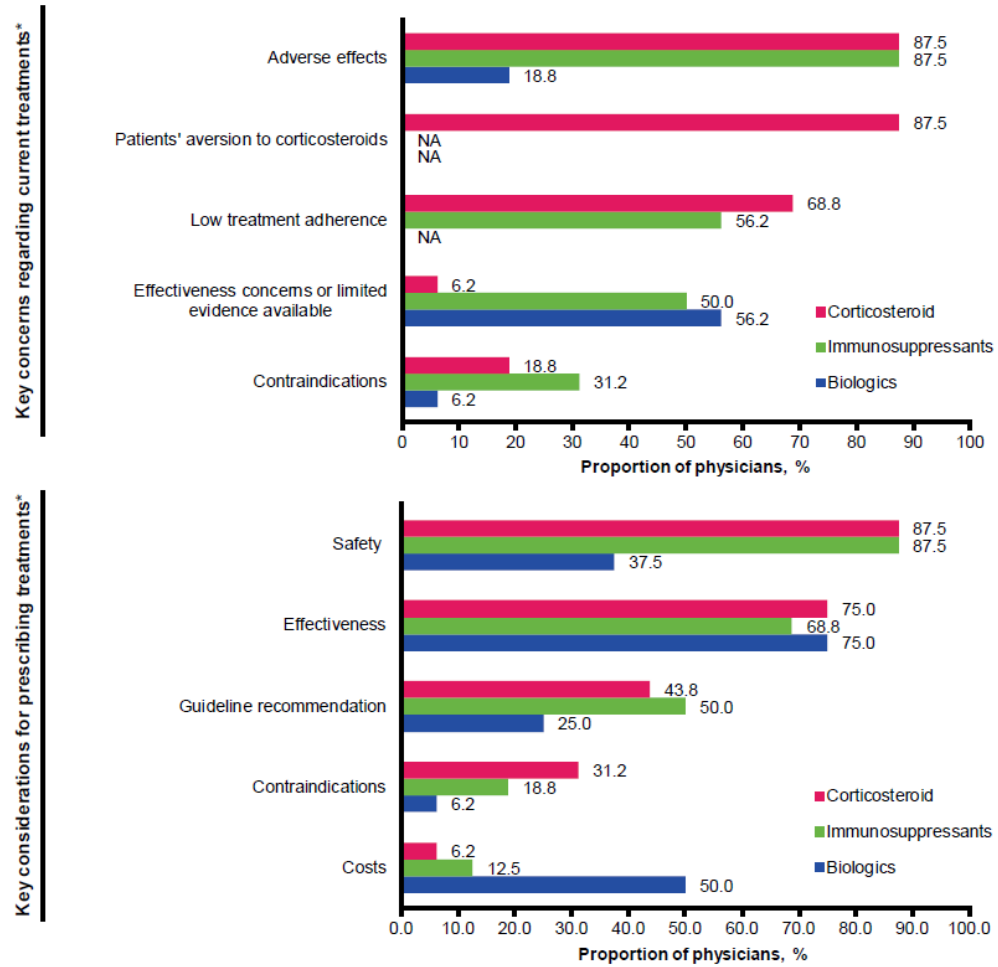

| | Cyclophosphamide | Prednisone | Methylprednisolone | IV immunoglobulins | Rituximab |
|---|---|---|---|---|---|
| No. of physicians reporting non-zero proportions, n | 14<br>14<br>14 | 12<br>NA<br>12 | 12<br>NA<br>11 | 8<br>7<br>6 | 5<br>4<br>4 |
| Treatment duration, months, median (range) | 6.0 (2.0, 18.0)<br>7.5 (3.5, 18.0)<br>6.0 (3.5, 18.0) | 4.5 (1.5, 18.0)<br>NA<br>6.0 (1.5, 24.0) | 4.5 (0.3, 18.0)<br>NA<br>5.0 (0.3, 24.0) | 1.0 (0.2, 2.0)<br>1.0 (0.2, 3.0)<br>1.0 (0.2, 6.0) | 12.0 (1.0, 18.0)<br>7.0 (1.0, 18.0)<br>7.0 (1.0, 18.0) |




| | Prednisone | Azathioprine | Methylprednisolone | Cyclophosphamide | Methotrexate |
|---|---|---|---|---|---|
| No. of physicians reporting non-zero proportions, n | 12<br>0<br>12 | 11<br>11<br>11 | 10<br>0<br>8 | 8<br>8<br>8 | 8<br>6<br>7 |
| Treatment duration, months, median (range) | 17.9 (1.5, 60.0)<br>NA<br>24.0 (1.5, 40.0) | 16.4 (1.5, 60.0)<br>24.0 (1.5, 36.0)<br>24.0 (1.5, 40.0) | 19.4 (6.0, 100.0)<br>NA<br>32.0 (15.5, 70.0) | 11.3 (2.0, 60.0)<br>18.0 (4.0, 60.0)<br>10.2 (4.0, 60.0) | 12.0 (1.5, 60.0)<br>24.0 (1.5, 30.0)<br>24.0 (1.5, 40.0) |

Data shown for the therapies with the 5 highest number of physicians reporting non-zero proportions.
*Aggregated patient statistics were reported by the number of physicians specified in tables.

## Figure 3. Adverse effects were a key concern for 87.5% of physicians towards both corticosteroids and immunosuppressants, while only 18.8% had adverse effect concerns towards biologics. Safety and effectiveness were the two most common considerations for prescribing corticosteroids and immunosuppressants




The top 5 physician responses are shown. *Participants were allowed to select more than one response; therefore, the total proportions may not sum to 100%.

# Collaboration with established national registries

An efficient setup to sustain long-term collaborative RWD efforts

# China's National Hemophilia Registry

Study 1: China's first real-world study including cost of hemophilia as an outcome,[1] which is also the first peer-reviewed publication from this long-established registry

Study 2: China's first real-world study to demonstrate the improvements in hemophilia management in the past decade[2]

Study 3: An overview of patients with hemophilia A in China: epidemiology, disease severity, and treatment strategies, based on the national hemophilia registry data[3]

**CNHR established**

2007

**166** hospitals

**31** provinces

Sep. 2018

**10K+** patients

**Historical information optimization**

Pinpointed key limitations and adapted an efficient data processing approach and supplementary data collection to strengthen the scientific value of current data

Dec. 2018

**Supplementary data curation**

**200+** hospitals

2020

**Publications**


Source:
1.Song X, et al. Real-world analysis of hemophilia patients in China: A single center's experience Running title: Real-world data of hemophilia in single center. DOI: 10.1111/hae.14029
2.Dou X, et al. Haemophilia care in China: Achievements in the past decade. DOI: 10.1111/hae.14101
3.Song X, et al. An overview of patients with hemophilia A in China: epidemiology, disease severity, and treatment strategies. Under review

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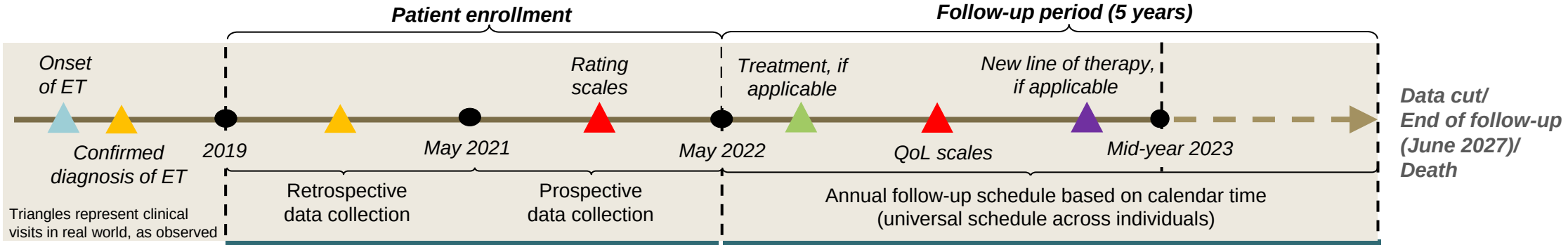
# The Essential Tremor Registry (CETR) in China

## Parkinson's Disease & Movement Disorders Multicenter Database and Collaborative Network in China

- An ambispective design with a retrospective and a prospective phase leads to a substantial sample size
- A clinical-research duo model enhanced the longitudinal design, effectively reducing loss to follow-up and enabling recruitment for *ad hoc* patient contacts
- A sophisticated data curation model is needed to establish connections between historical and prospective data
- A nested cohort design with hospital data linkage is key to minimize bias due to non-individualized follow-up

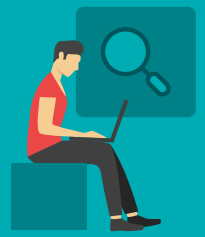



| Enrollment period (2019 – May 2022) | Follow-up period (May 2022 – May 2027) |
|---|---|
| • Demographic characteristics<br>• Dietary and environmental exposure history<br>• Disease and clinical characteristics<br>• ET rating and other symptom measures<br>• Lab and imaging tests<br>• Treatment information, if available | • Dietary and environmental exposure history, if available<br>• Disease and clinical characteristics, if available<br>• ET rating and other symptom measures, including QoL rating<br>• Lab and imaging tests, if available<br>• Treatment information, if available<br>• Health care utilization |

**Abbreviations:** ET, essential tremor; HRU, healthcare resource utilization; QoL, quality of life.

# Key Takeaways

Challenging data landscape with fragmented and low-quality RWD



Be mindful of limitations and risks associated with existing data sources

Implement comprehensive and nimble approaches to achieve short-term and long-term objectives

Timely RWE is key to support pre-launch and post-launch communications and decision making

Early research engagement with KOLs is vital, and collaborative research is an effective model for building collaboration

Take actions to curate fit-for-purpose RWD through integrated solutions 2–3 years before launch

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# Part III – Advancing Real-World Evidence Generation: Insights From France and Europe

Grégoire Mercier, M.D., Ph.D.

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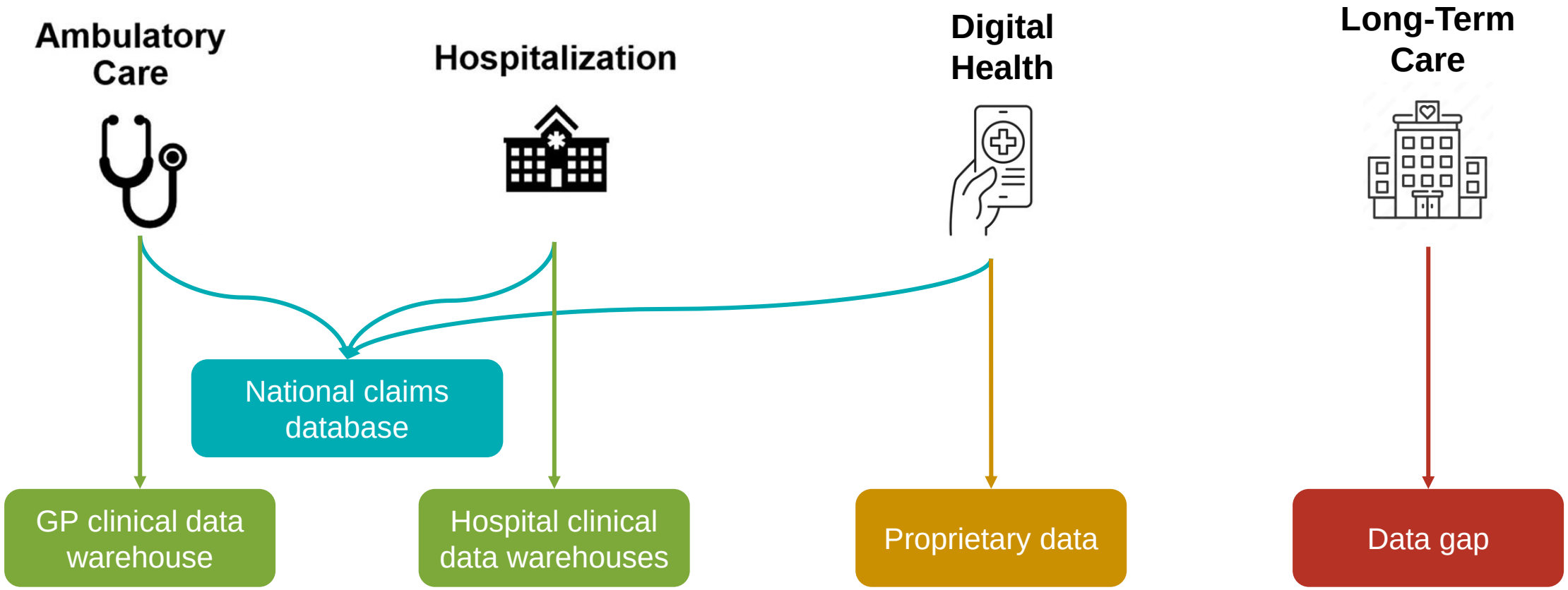
# Conflict of interest disclosure

| | |
|---|---|
| Grant/Research Support | Roche, Gilead |
| Consulting Fees/Honoraria | Gilead, Roche, Pfizer, Air Liquide, IQVIA, Analysis Group, Alira Health, L.E.K. Consulting, MindMaze |
| Major Stock Shareholder/Equity | KanopyMed |
| Royalty Income | 0 |
| Ownership/Founder | KanopyMed |
| Intellectual Property Rights | 0 |
| Other Financial Benefit | 0 |

# A primer on real-world data in France



# National claims database (SNDS)

**Ambulatory Care**

**Outpatient claims database**
- Demographics
- Chronic diseases registration
- Medical + non-medical encounters
- Rx, medical devices
- Lab tests, transportation
- Incl. dates, costs, professional ID

**Hospitalization**

**Hospital discharge summaries database**
- Acute & post-acute care
- Diagnoses
- Procedures
- Wards & ER
- Incl. dates, costs, hospital ID

**Death Certificates**

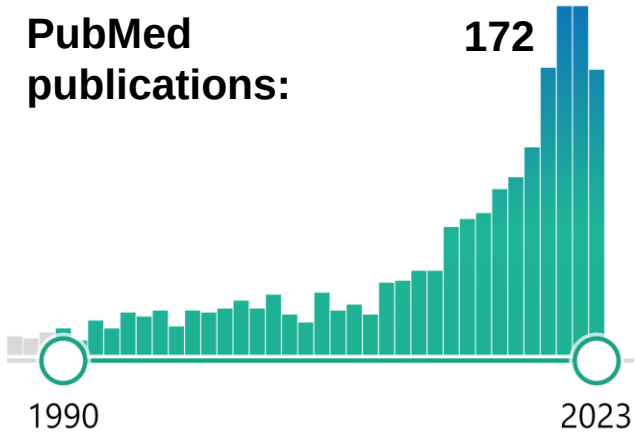
**Death registry**
- Date of death
- Causes of death

**National claims database**
- 99% of total population (~66 million)
- Unique patient ID
- 10 to 20 years in depth

SNDS
Système national des données de santé

HEALTH DATA HUB

**PubMed publications:** 172



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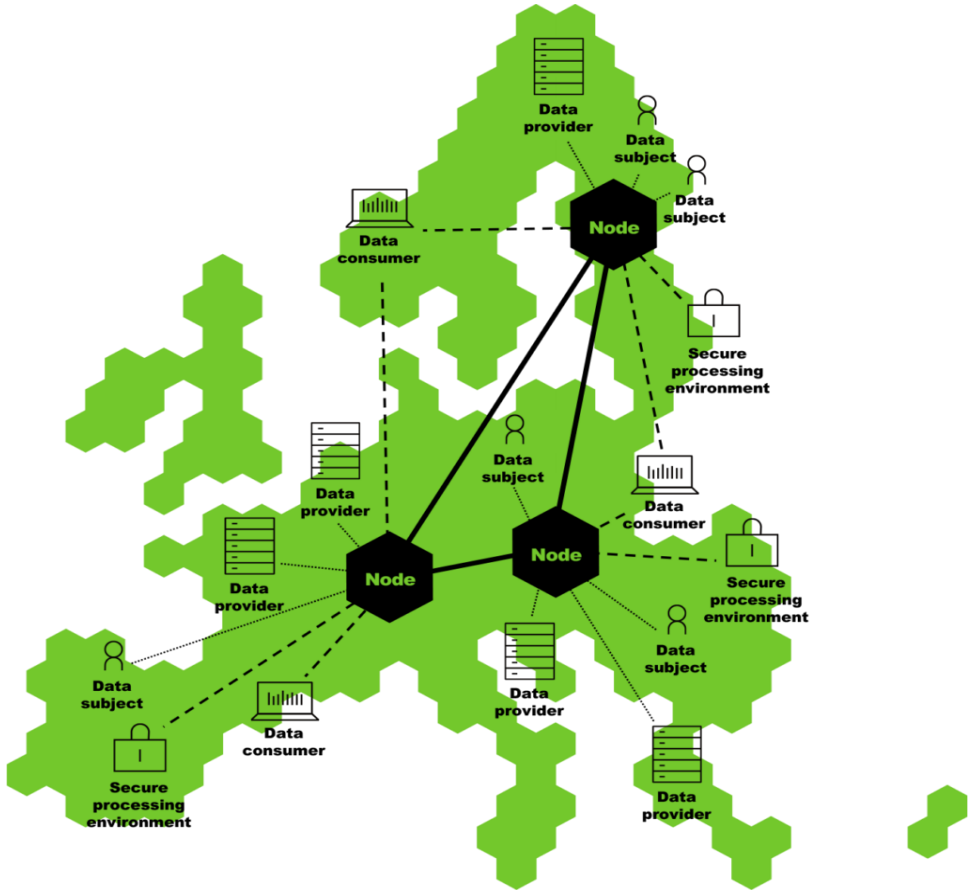
EHDS
HealthData@EU Pilot

# From SNDS to EHDS

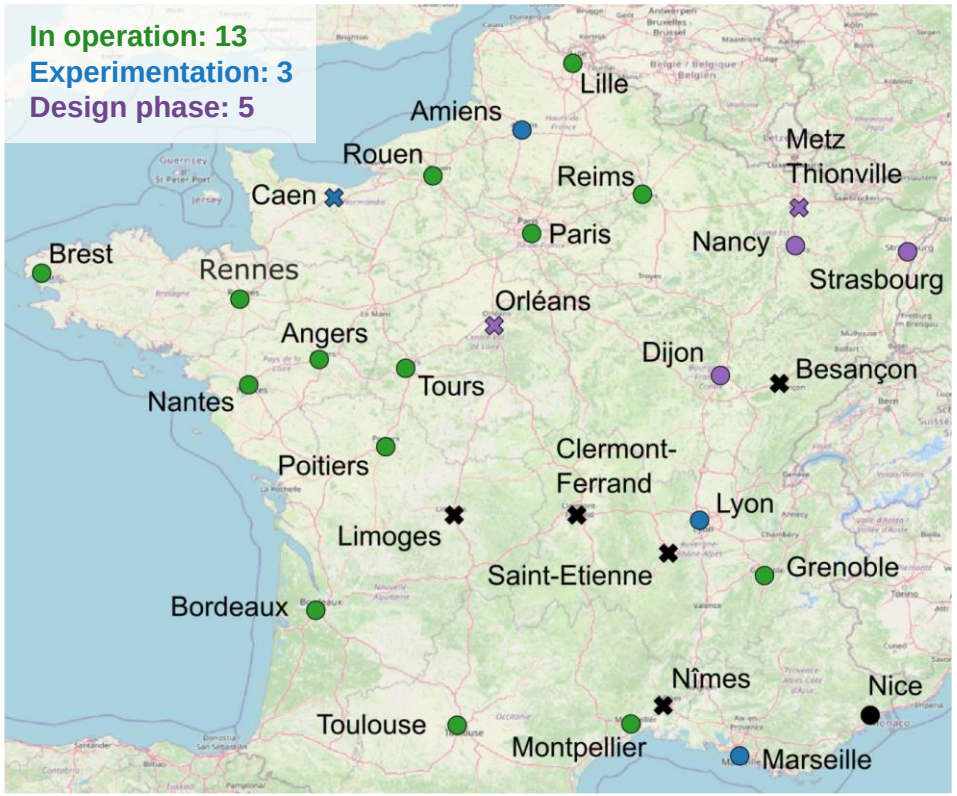



- **European Health Data Space**
- Goal: **to promote new digital health services and enable GDPR-compliant access to health data**
- France: Health Data Hub
- V1 expected **by 2025**

# Hospital clinical data warehouses (CDW)

**Hospitalization**

Hospital clinical data warehouses




*Source: Doutreligne, et al., 2023*

- Standardization towards the **OMOP** Common Data Model
- Public funding
- Emerging **business models** for hospitals
- In line with the European **EHDEN** project

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# Hospital CDW: Core common dataset (1)

## Socio-demographic data

- NIR/INS
- Twin row
- Date of birth
- Date of death

## PMSI base

- Age
- Acts
- Gender
- Start date of stay
- Diagnosis
- Date of end of stay
- Entry mode stay
- Exit mode stay
- Geographical code of residence

## Biology results

### Renal function

- Urea dosing
- Creatininemia
- DFG

### Glycemic control

- Fasting blood glucose
- Glycated hemoglobin

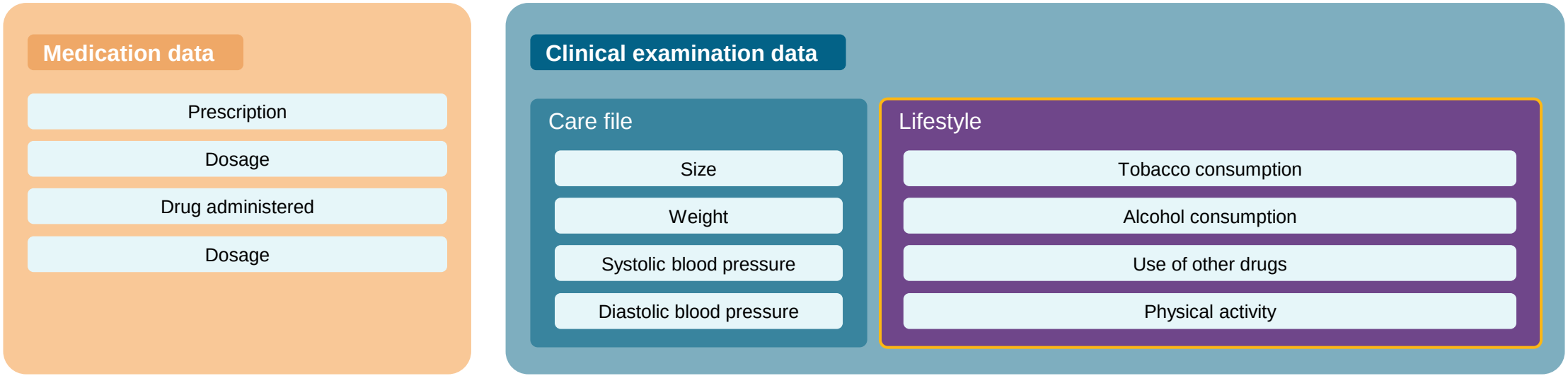
### Liver check-up

- GGT
- Conjugated bilirubin
- AST
- Total bilirubin
- ALT
- PAL

### Blood count

- TCA
- Red blood cells
- Lymphocytes
- Leukocytes
- VGM
- Eosinophils
- Hemoglobin
- Inserts
- Monocytes
- Hematocrit
- Neutrophils
- TP

# Hospital CDW: Core common dataset (2)



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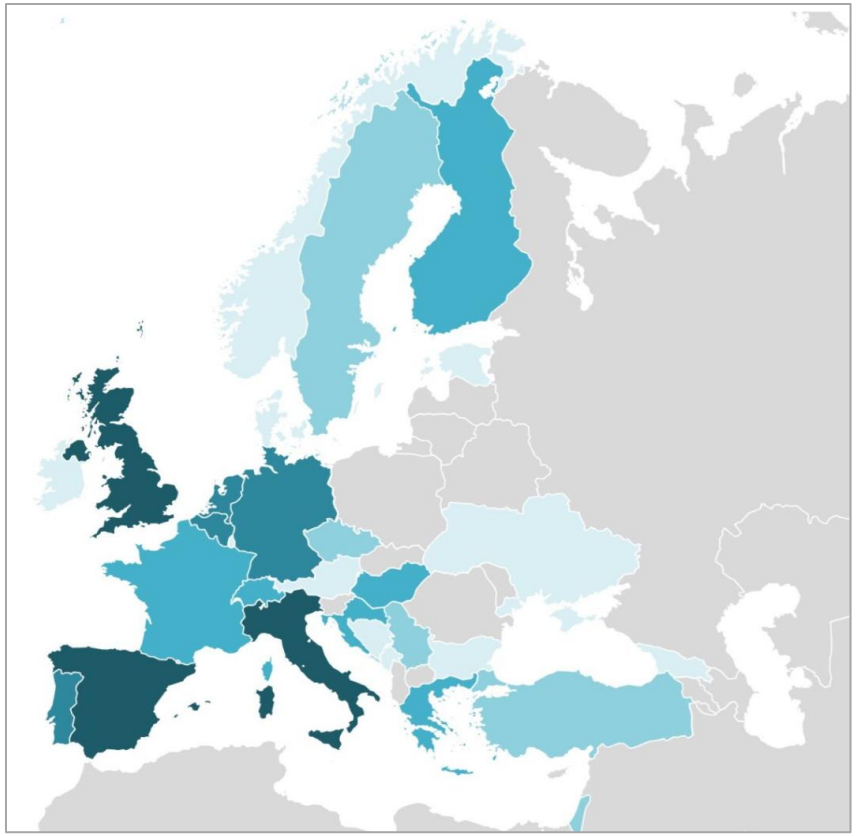
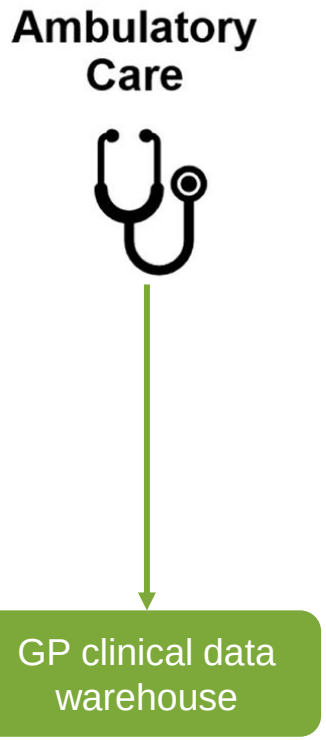
EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

# The EHDEN European project

- Goal: **To harmonize source data, at scale, to the OMOP common data model, within a federated network**
- To date: 187 data partners from 29 countries
- In France:
  - Paris
  - Montpellier
  - Bordeaux
  - Lille
  - Toulouse



# Ambulatory care clinical data warehouse: P4DP




P4DP
Platform for Data in Primary care

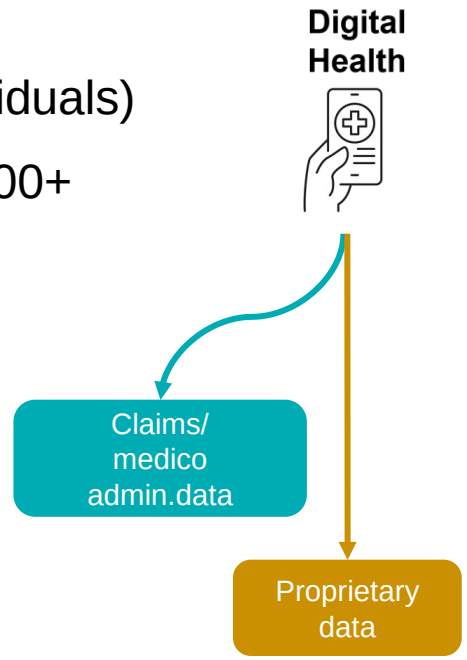
- Goal: **to create a nationwide GP clinical data warehouse**
- Partners: GP network, universities, companies, Health Data Hub
- Government-funded
- **OMOP** Common Data Model
- Data-sharing agreements and business models for GPs
- V1 expected **by 2025**

## Cohorts and registries

- 30+ national cohorts
- Population-based, e.g., CONSTANCES (200,000 individuals)
- Disease-based, e.g., HEPATHER (liver diseases, 21,000+ patients)
- Challenges:
  - Access to data
  - Interoperability
  - Patient-level linkage

France Cohortes
Données de recherche en santé publique

## E-Health




- Billing data in SNDS:
  - Telehealth
  - Home monitoring
- Mostly proprietary data
- Challenges:
  - Access to data
  - Data quality

# Wrap-up and take-home messages

- **National claims database**: the most powerful RWD source
- **Hospital CDW**: towards a European network
- **Primary care CDW** is the next frontier
- **Current challenges**:
  - Standardization
  - Access to data
  - High-performance calculation
  - Patient-level matching across data sources
- **Data gaps**: long-term and social care, exposome, social determinants of health….

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# Thank you!

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# Questions?