PHARMO DATA NETWORK

A group of well-established, clinically-rich linked databases

YOUR EXPERIENCED GLOBAL RESEARCH PARTNER

Access to large, representative, clinically rich patient-level data in Europe remains a challenge for pharmaceutical manufacturers anxious to utilize Real World Data (RWD) to support regulatory and market access needs. Where options do exist, there is generally a trade-off between breadth (coverage) and depth (clinical richness) of the data.

'Broad' datasets often generated from a single source, like claims, are often not clinically or longitudinally rich enough to address complex conditions. 'Deep' datasets are generally narrow, e.g., covering one treatment setting in only one geography. There are, of course, exceptions, e.g., the well-known Swedish healthcare data, but access to multi-setting, clinically robust, longitudinal RWD from non-Nordic countries remains a large unmet need for pharmaceutical manufacturers.

The PHARMO Institute, part of Lumanity, is your first-choice research partner to address and coordinate your need.

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UNIQUE ATTRIBUTES

The PHARMO Institute, with its exclusive and unparalleled access to Dutch healthcare data – both large (10m persons) and representative of the overall population (approximately 25% coverage geographically distributed) Dutch healthcare data are gathered across multiple settings, enabling a full picture of the patient journey and, consequently, healthcare resource utilization (HCRU). The data are structurally linked across myriad sources spanning disease-specific registries (including oncology, perinatal); pathology and clinical laboratory settings; mortality; and social determinants of health. In addition, linkage to patient-reported outcomes (PROs) is possible. PHARMO, having worked extensively in diabetes, heart failure, rare disease and across a broad set of indications in oncology, has already built curated datasets that can be tapped into quickly to address research objectives in those disease states.

And, of course, analyses using PHARMO data are backed by scientific rigor (member of European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, authoring 600+ papers, with 12-15 PhDs in-house) and subject to the highest standards for General Data Protection Regulation compliance.

Coverage

10m active persons (dossiers) approximately 25% of population

Distribution across all **12 provinces**

Multi-setting

GP, hospital, ambulatory, in-patient & outpatient pharmacy, and some secondary care (hematology-oncology perinatal and maternal)

Temporality

Low lag

- Yearly linkage and update
- GP data (e.g., outcomes,events) refreshed monthly

Longitudinal

Cradle to grave on 450k persons;
>10m persons with 12 years average follow-up

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Clinical depth

Pre-established structural linkages with Oncology , Pathology, and Perinatal registries

- Netherlands Cancer Registry hosted by the Netherlands Comprehensive Cancer Organisation includes data on diagnosis, tumor staging, tumor site, morphology, at diagnosis, and treatment received directly after diagnosis. The data are accessible with a 1-year lag
- Pathology Registry hosted by PALGA includes excerpts of histological, cytological and autopsy examinations
- Perinatal Registry hosted by Perined provides insights on pregnancies, births, and neonatal outcomes of births

Clinical laboratory

- Actual test results available (unlike claims data)

Social determinants of health

- Linkages possible with external data e.g. National Statistics (Central Bureau of Statistics)
- In-house geoscience environmental health data

PROs

- Potential to go back to medical files to collect additional information
- Validation of outcomes

Mortality

- Linkage with mortality registry as well as in-hospital deaths

Regulatory and payer acceptance

Pharmacovigilance Risk Assessment Committee approved

Data Analysis and Real World Interrogation Network member (DARWIN)

European Medicines Agency recommended

Health Technology Assessment accepted

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

enepp

Ease of use

Pragmatic feasibility

Speed to analysis (6-8 mo.) and timely refresh

Low bureaucracy (pre-defined governance)

Innovation friendly

Powers a range of RWE use cases

- Post-authorization safety and efficacy (PASS, PAES) and drug utilization review (DUR)
- Incidence/prevalence, treatment patterns, and patient pathways
- Comparative effectiveness, including synthetic control arms
- Healthcare resource use and cost of illness research
- Validation of surrogacy outcomes
- AI patient finding, classification, and disease progression prediction

Tailor made cohorts (e.g., COVID-19 including vaccines, daily tests, etc.)

EXAMPLES OF SELECTED INDICATIONS

Hard-to-find data readily available in PHARMO linked datasets

Oncology

Breast 40,000*
Prostate 32,500*
Lung 36,000*

- **Performance status/risk scores** (e.g., WHO, International Prognostic Index, Karnofsky Index)
- **Blood-based biomarkers** (e.g., EGFR, HER2)
- **Biopsies** (e.g., solid tumor samples, bone marrow)
- **Specific laboratory values** in serum, urine or bone marrow for determining diagnosis and/or risk classification such as blasts, hyperplasia, thrombus levels, neutrophils, etc.

Hematology

NHL 9,200*
MM 35,000*

Diabetes

T1D 22,000*
T2D 290,000*

- **BMI**
- **Blood pressure**
- **Glycemic control** (e.g. HbA1c)
- **Lipids** (LDL, HDL)
- **Continuous glucose monitoring**
- **Complications and comorbidities of diabetes** (e.g., cardiovascular disease, obesity, kidney disease)
- **Multi-setting healthcare resource use** (incl. specialist visits e.g., endocrinologist, ophthalmologist)
- **Date, dosage, and quantity of in-patient/ outpatient medications** (GLP1, SGLT2, biguanides, sulfonylureas, TZDs, DPP-4)
- **Adherence/persistence**

Cardiovascular

Heart Failure 79,000*
Stroke 90,000*

- **BMI**
- **Blood pressure**
- **Lipids** (LDL, HDL)
- **Triglyceride**
- **Total cholesterol**
- Medical device use
- **Health indicators** (e.g., smoking, physical fitness)
- **Drug utilization** (e.g., lipid lowering tx; concomitant medication use e.g., hypertensive, anti-thrombotic, anti-diabetic)
- **Adherence/persistence**

Central Nervous System

Alzheimer's 11,000*
Parkinson's 16,000*
MS 5,000*
Depression 338,000*
Migraine 138,000*

- **Longitudinality** – captures slow progression and lookback on average 20 years
- **In-patient and outpatient drug exposure** (e.g., AChE inhibitors, memantine, statins, anti-anxiety/psychotics, evodopa, dopamine agonists, MOA-B inhibitors, anticholinergics, COMT inhibitors)
- **Symptoms of early disease** (e.g., mild cognitive impairment, short-term memory loss, lack of awareness, head trauma, comorbidities such as diabetes, depression, anxiety, psychosis)
- **Multi-setting healthcare resource use**

Respiratory

COVID-19 360,000*
COPD 75,000*
Asthma 180,000*

- FEV1, FVC, PEF
- Acute exacerbations
- Disease severity i.e. GOLD classification
- CCQ and ACQ scores
- Adherence/persistence

Nephrology

CKD 90,000*

- **Pathologically confirmed diagnoses** (e.g., subtypes of CKD, such as IgAN)
- **CKD stage classification** (inc. progression to ESRD)
- **Concomitant medication** (e.g., heart failure, diabetes)
- **Labs** (e.g., blood pressure, UACR, HbA1c, creatinine, eGFR, proteinuria)
- **Hospital events** (incl. renal failure)

Maternal Care

Pregnancies 540,000*
Children 126,000*

- **Mother demographic and clinical characteristics** (e.g., maternal age, obstetric history, parity)
- **Pregnancy** (e.g., mode of conception/delivery)
- **Child demographic and clinical characteristics** (e.g., birthweight, gestational age, Apgar score)
- **Miscarriage/abortion**
- **Mother-child link**

*Patient counts between 2013-2023
Final cohort size for any study will depend on the data sources included

CASE STUDY

MULTI-SETTING BREAST CANCER PATIENT PATHWAY

The client

Large innovative global healthcare company with substantial oncology portfolio

The scientific challenge

With the introduction of investigational HER2 targeting treatments, thorough understanding of breast cancer with different HER2 expression levels is critical, specifically:

- Adverse events
- Treatment pathway
- Healthcare resource utilization

Our approach

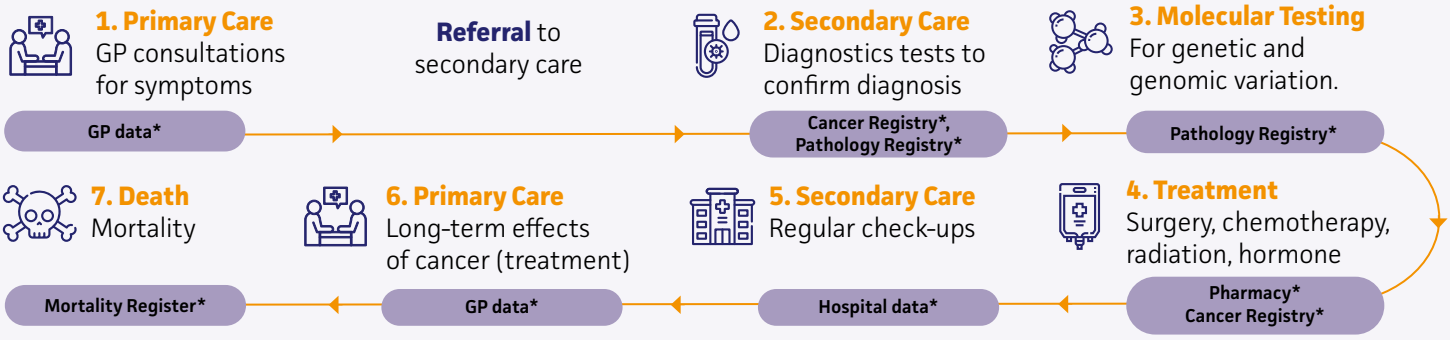
- Distant metastatic breast cancer cases selected from Pathology Registry
- Text-mining of pathology reports to categorize cases into HER2 IHC0, HER2-low or HER2+
- Treatment pathway established by linking information from both in and out-patient pharmacies
- Long-term adverse events and healthcare resource utilization from hospital data

The valued outcomes

1. **Large cohort of breast cancer patients with longitudinal data from different settings:**
   - Pathology
   - In and out-patient pharmacies
   - Hospital
2. **Possibility to categorize by HER2-status**

- Most previous studies only distinguished between HER2+ and HER2 negative breast cancer, we included HER2-low as a subcategory within HER2 negative, to get more insight in the biology of HER2-low breast cancer

Short and long-term follow-up and management after breast cancer diagnosis



PHARMO's unique linkages enable visibility of the full patient journey, moving through different settings of care to observe prior to diagnosis all the way through long-term management and beyond.

*Data source

CASE STUDY

SUPPORTING TIMELY DIAGNOSIS OF SLOW-PROGRESSING ALZHEIMER'S DISEASE

The initiative

ABOARD: A Personalized Medicine Approach for Alzheimer's Disease

The scientific challenge

- Alzheimer's disease is **slow progressing**, taking ~30 years to develop
- GPs play an important role in **early recognition** of AD
- Early diagnosis supports optimized treatment that can sustain **cognitive function** for longer, address symptoms, and **improve quality of life**
- **Longitudinal historical RWD pre-diagnosis** is sparse but crucial to determine whether timelier diagnosis is possible

Our approach

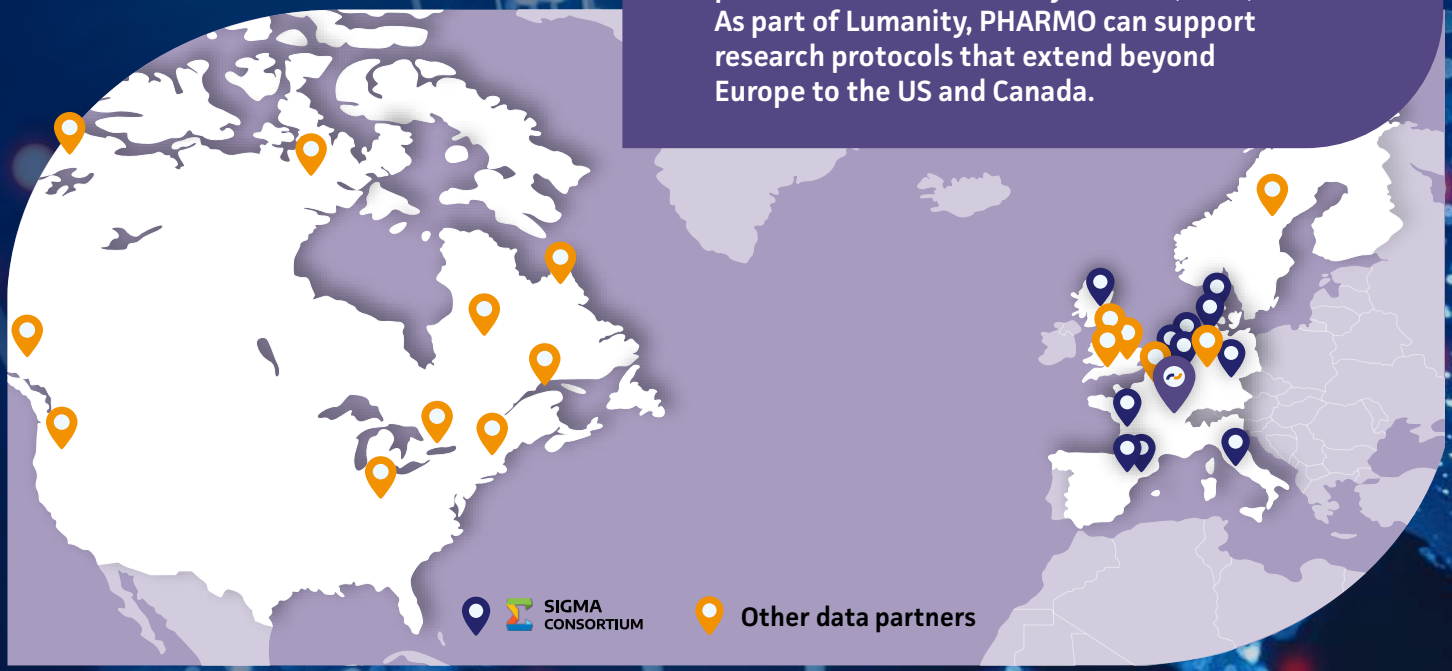
- Bespoke curation of dementia cohort using:
  - GP recorded diagnosis for dementia
  - Free text notes for dementia or subtype
  - Anti-dementia drug prescriptions
- Characterization of primary care patient pathway prior to a diagnosis being made

The valued outcomes

1. **Multi-country insights generated through international research collaboration. Across all participants, PHARMO Data Network provides the largest cohort (n>70,000)**
2. **Ability to look back 20 years**
3. **Research with meaningful impact on patient outcomes**
   - Supports GPs in identifying red flags for dementia
   - Changes the disease progression trajectory for patients: with earlier diagnosis comes improved prognosis and patient outcomes

GLOBAL RESEARCH COLLABORATIONS AND PARTNER AGNOSTICISM – FLEXIBLE MODEL TO WORK WITH ANY DATA SOURCE

PHARMO is a member of the SIGMA consortium and a coordinating center for multi-country post-authorization safety studies (PASS) and post-authorization efficacy studies (PAES). As part of Lumanity, PHARMO can support research protocols that extend beyond Europe to the US and Canada.



The best method to assess the value of a clinical dataset/network is to test it in action by finding patients relevant to your research needs.

We invite you to do just that - reach out to PHARMO and share your research questions, and together we can find the most relevant patients and advance your research plans.

Get in touch

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