TEDDY NETWORK

TEDDY General Assembly and Scientific Meeting

DARWIN EU project - from real-world evidence to better medicines in Europe

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INSTYTUT „POMNIK-CENTRUM ZDROWIA DZIECKA"

What DARWIN EU is — and why it matters

- The European Medicines Agency (EMA) and the European Medicines Regulatory Network in 2022 established a coordination centre (Erasmus University) to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the EU.

- This capability is called the **Data Analysis and Real World Interrogation Network - DARWIN EU**

DARWIN EU

The goal for DARWIN EU is to support regulatory decision making by:

- establishing and expanding a catalogue of observational data sources for use in medicines regulation;
- providing a source of high-quality, validated RWD on the uses, safety and efficacy of medicines;
- addressing specific questions by carrying high quality, non-interventional studies, including developing scientific protocols, interrogating relevant data sources and interpreting and reporting study results.

DARWIN EU

- The network works with hospitals, registries, databases, biobanks and other RWD sources.
- **Data partners standardize data to the OMOP Common Data Model.**
- Regulators use the resulting reports to complement other evidence in decision-making.
- DARWIN EU has now onboarded **40 data partners**; onboarding has been completed in 2025.



DARWIN EU RWD studies

	Category	Description
	Off-The-Shelf Studies	These are mainly characterisation questions that can be executed with a generic protocol. This includes studies on disease epidemiology, for example the estimation of the prevalence or incidence of health outcomes in defined time periods and population groups, or drug utilization studies at the population or patient level.
	Complex Studies	These are studies requiring development or customisation of specific study designs, protocols, analytics and phenotypes. This includes studies on the safety and effectiveness of medicines and vaccines.
	Routine Repeated Analyses	Routine analyses based on Off-The-Shelf or Complex Studies (see above), which are repeated with a pre-specified regularity (e.g. yearly)
	Very Complex Studies	Studies which cannot rely only on electronic health care databases, or which require complex and/or novel methodological work

DARWIN EU RWD studies

DARWIN EU® study

Is there a link between blood clots and common painkillers with hormonal birth control



Is There A Link Between Blood Clots And Common Painkillers In Women Who Use Hormonal Birth Control

Venous thromboembolism (VTE) is when a blood clot forms in a deep vein. VTE is rare, but it can be life-threatening. Often, it can be prevented. Research has found that taking oral combined...

Updated 2026-03-30

DARWIN EU® study

Is there a risk of suicidality after taking the antibiotic doxycycline



Is There A Risk Of Suicidality After Taking The Antibiotic Doxycycline

Doxycycline is a broad-spectrum antibiotic, widely used to treat bacterial infections. It can be used for treatment of moderate or severe acne. Based on spontaneous case reports,...

Updated 2026-03-30

DARWIN EU® study

Overall survival in patients with NSCLC treated with selected immunotherapies



Overall Survival In Patients With Non Small Cell Lung Cancer Treated With Selected Immunotherapies As First Treatment

Better understanding of lung cancer has led to new treatments, but more knowledge is needed on the effectiveness of medicines used to treat non-small cell lung cancer (NSCLC) in real-worl...

Updated 2026-03-30

Is there a risk of suicidality after taking the antibiotic doxycycline



DARWIN EU

Why is this study needed?

Doxycycline is a broad-spectrum antibiotic, widely used to treat bacterial infections. It can be used for treatment of moderate or severe acne.

Based on spontaneous case reports, recent concerns have been raised about its side effects, particularly suicidality, but the data have been limited.

How were the results used?

The study helped PRAC assess whether doxycycline might be linked to suicidal thoughts or behaviour. The committee concluded that the current evidence is not sufficient to establish a causal relationship between doxycycline and the risk of suicidality.

How was this conducted?

The study generated more information to understand if the medicine is linked to an increased risk of suicidality. It looked at people who started taking doxycycline and compared their risk to people taking other medicines for treating acne or infections. It also considered the different health conditions the medicine is used to treat. Data from 3 European countries were analysed.

Why do these results matter?

The study helped alleviate safety concerns and reassured patients using the medicine. This is important as the medicine is commonly used to treat acne, urinary tract and respiratory infections.

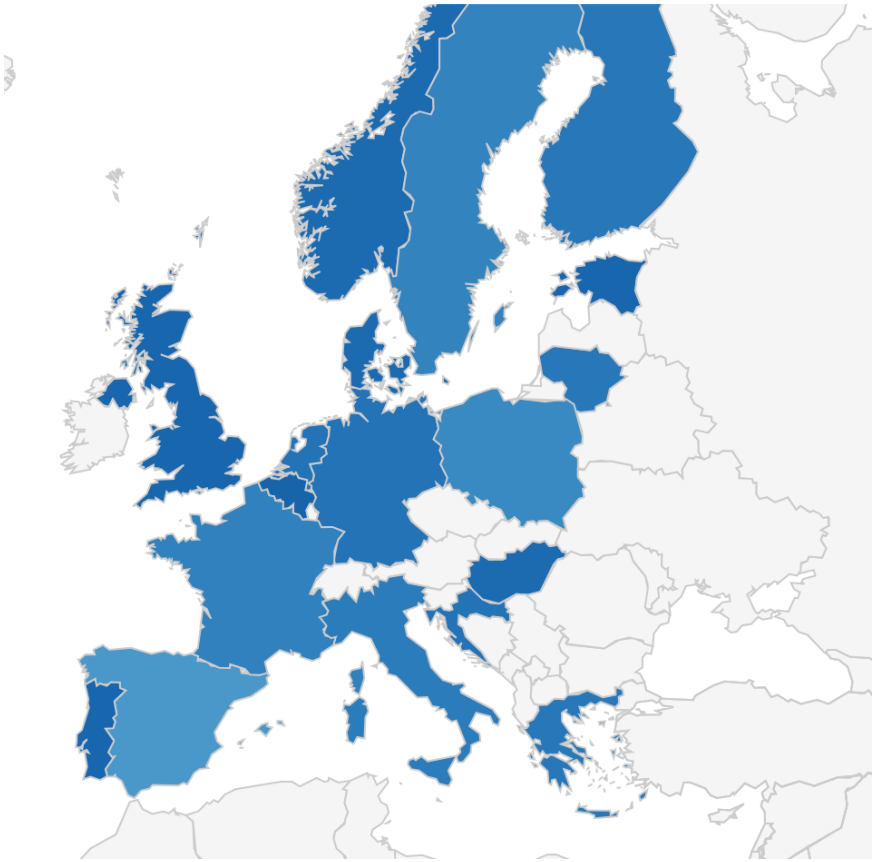
CMHI – partner in the Darwin EU project

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Poland

IPCZD

- **Name:** Children's Memorial Health Institute Database
- **Type:** Inpatient (Hospital) Care
- **Total number of persons:** 1,020,100
- **Coverage start:** 2020



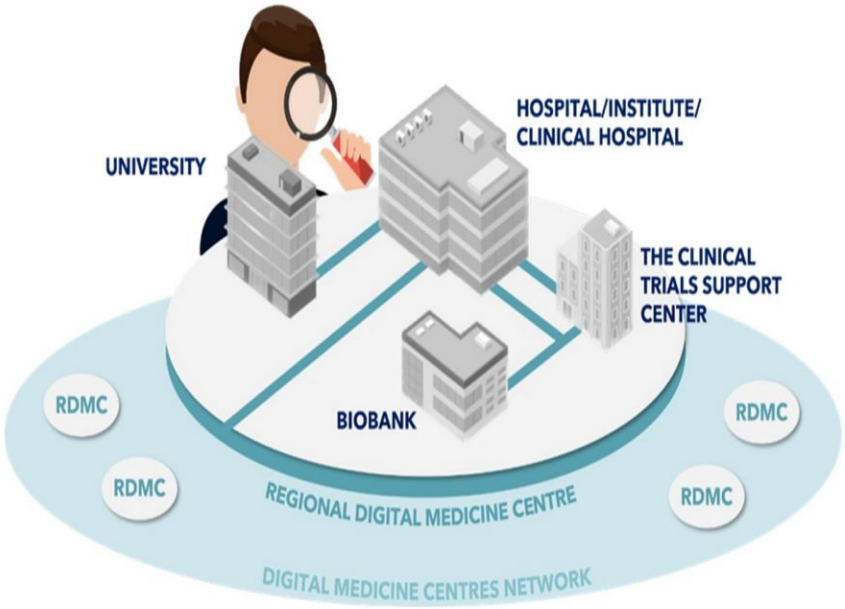
Why our hospital decided to apply

- CMHI is one of the largest paediatric centres in Poland, with strong research activity and 7 ERN memberships.
- Our database has a strong paediatric profile, including neonates and rare diseases; it also supports permanent family linkage.
- We are a national referral hospital — our patients come from across Poland.
- PeRCMC created the strategic and organisational framework to make this application meaningful.
- We applied because we want our local data work to contribute to European evidence generation, not remain only internal.

Paediatric Regional Center for Digital Medicine (PeRCMC) at the CMHI

MEDICAL RESEARCH AGENCY

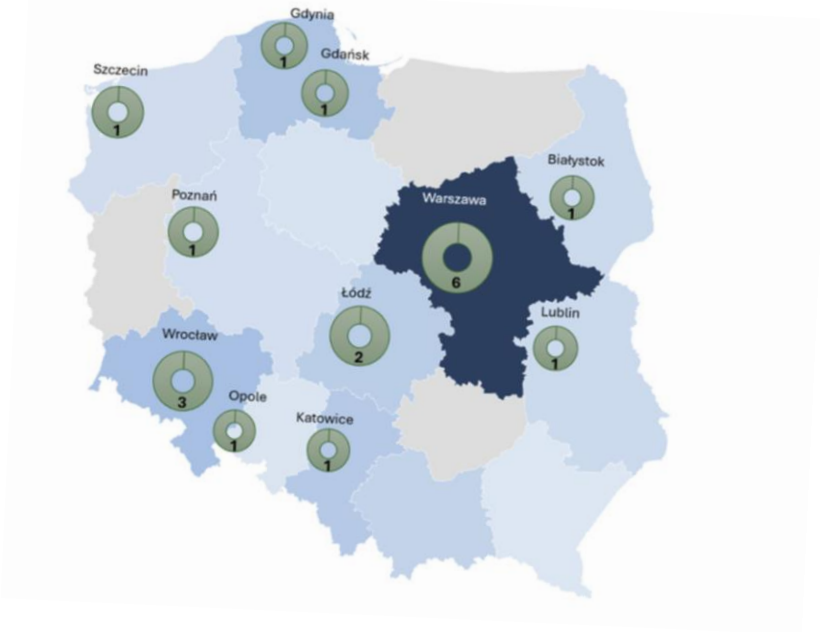
- PeRCMC at the CMHI - founded by the Medical Research Agency – contract for 5 years starting in November 2023, budget 8 milion Euro
- A coherent digital medicine ecosystem proposed



Paediatric Regional Center for Digital Medicine (PeRCMC) at the CMHI

MEDICAL RESEARCH AGENCY

- PeRCMC at the CMHI – member of the national network founded by the Medical Research Agency
- The Regional Digital Medicine Centres (RDMCs) are an initiative of the Medical Research Agency to develop a digital infrastructure for biomedical research with a particular focus on clinical trials and the efficient management of large health and biomedical datasets.



PeRCMC at the CMHI

- Strategic CMHI initiative advancing paediatric digital medicine research.
- Development of IT infrastructure, building of competent team, biobank, and AI-driven projects.
- Integration of clinical, genetic, and imaging data from hospital systems for research purposes.
- Development of AI tools to support research, diagnostics, and clinical care.
- National and international collaborations for a future-proof ecosystem.
- Mission: accelerating research, innovation, and safe, data-driven paediatric medicine.

PeRCMC at the CMHI - staff & infrastructure



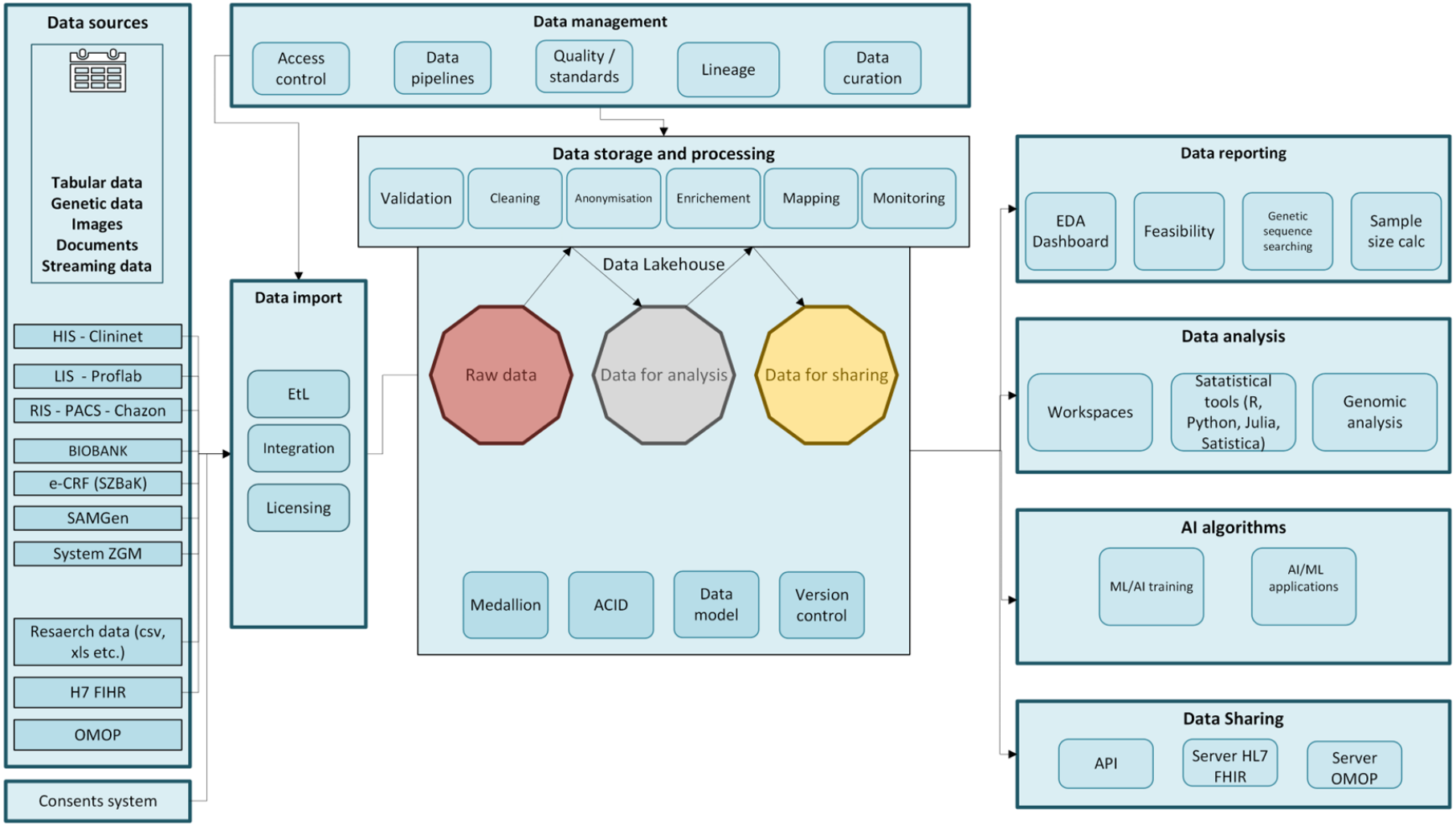


Stefan Marynowicz - data scientist
Elżbieta Birgiel - data engineer
Małgorzata Jarończyk - biostatistician
Katarzyna Turos - project coordinator
Artur Kaczorek - data manager/data administrator
Rafał Bartczuk - Manager of the PeRCMC
+ 32 persons working in the Scientific Research Department
+ 16 IT specialists

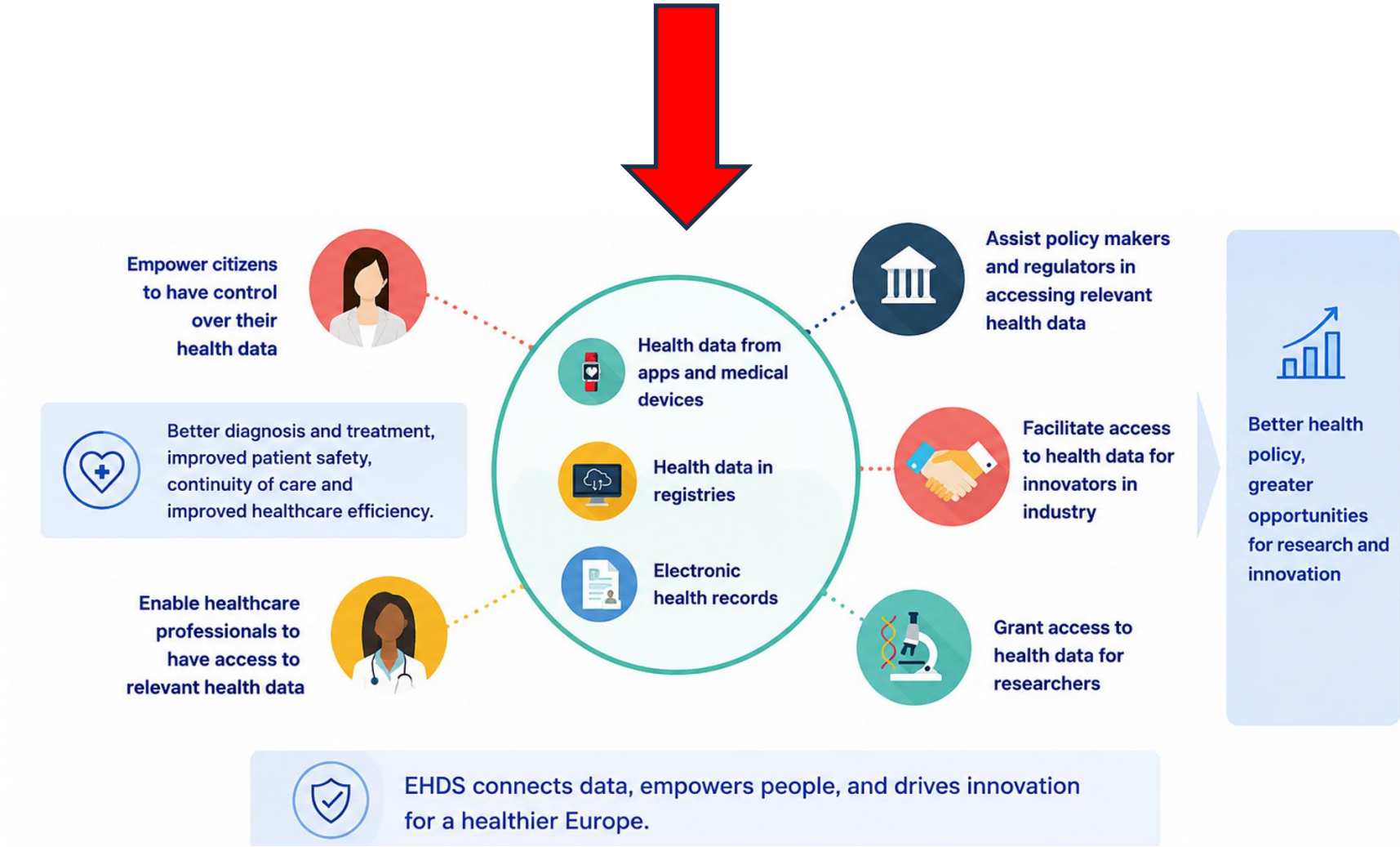
PeRCMC at the CMHI - scope of activities

- Analysis of omics data: genetic, epigenetic, transcriptomic, proteomic, metabolomic.
- Integration of data from different sources: telemetry, monitoring devices, individual patient surveys and data on biological material stored in biobanks, clinical trials.
- Implementing artificial intelligence (AI): developing predictive models and diagnostic algorithms to support clinicians in making therapeutic decisions.
- Support for clinical trials: optimising study designs and ensuring the quality of results at every stage of implementation.
- Data security: applying strict safety procedures in accordance with EU and national regulations.
- Use of data from Hospital Information Systems (HIS): Analysing information including demographic data, disease classifications (ICD-10), rare diseases classification (Orpha codes), procedures performed (ICD-9), administered medications (EAN code), and results of laboratory, imaging, and histopathological diagnostics.

PeRCMC at the CMHI - flow of data



CMHI - preparation for the EHDS



Thank you for your attention!!!

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