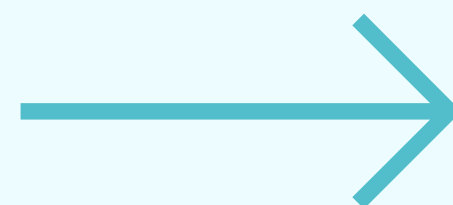




PHEMS FAQs



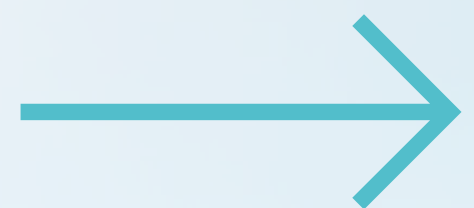


Why is PHEMS needed?

There is an urgent need for **PHEMS** because children and young people face **unique challenges when it comes to accessing high quality healthcare**. Some of these include:

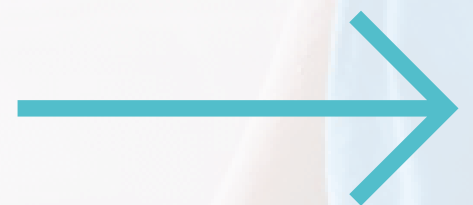
- ▶ **Small numbers of pediatric patients with rare and complex diseases**, limiting the research and development.
- ▶ **Lack of real-world data for HTAs** to evaluate new and costly therapies.
- ▶ **Need for increased engagement with MedTech and other** industries to support innovation.
- ▶ Small numbers of children's hospitals, making **benchmarking to improve system performance challenging**.

PHEMS will address these challenges through the creation of the **Pediatric Health Data Space (PHDS)**, ensuring every child has the best chance at a healthy start in life.



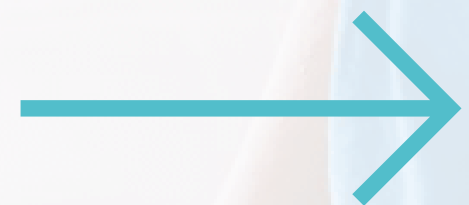


What is the benefit of the Pediatric Health Data Space (PHDS) to patients?



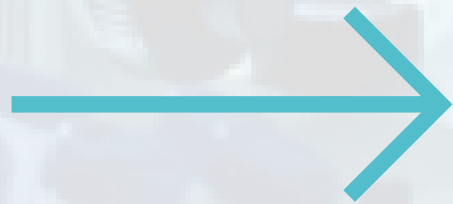
The **benefits** of the PHDS to patients will come from **increased research innovation** that improve health outcomes and healthcare delivery for children and young people. Examples of this include:

- ▶ **Accelerating clinical research**, especially in rare and complex conditions with small patient populations.
- ▶ **Improving hospital quality and efficiency** through increased capacity to benchmark.
- ▶ **Increasing access to new therapies and treatments** by supporting development of clinical trials.
- ▶ **Increasing application of machine learning and artificial intelligence** to allow for more personalized medicine.





What does it take to join PHDS?

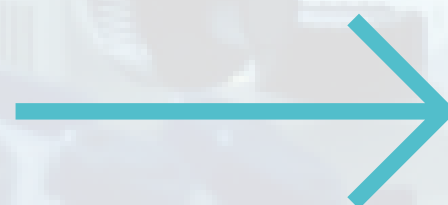


At the moment, we are **still constructing the PHDS** and the **PHEMS project is only open to members of the consortium**. We are working on the legal documents and Playbook that will allow other hospitals to join in the future.

In the meantime, you can **begin getting your hospital ready to join** by:

- ▶ **Starting to harmonize your data with OMOP.**
- ▶ **Assessing your technical capabilities, such as being able to run the federated node.**

You can learn more about getting your hospital ready by watching our Meet-Up on the topic **here** .





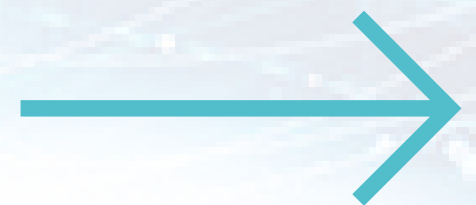
Why was OMOP selected to harmonize data?



The Observational Medical Outcomes Partnership (**OMOP**) **common data language model** was selected because:

- ▶ **Widely used to harmonize healthcare data**, so it has a large vocabulary. It is also used by multiple other projects and agencies, such as the **European Medicines Agency**.
- ▶ Therefore, **any work done standardizing data to OMOP** can also be **applied to other projects outside of PHEMS**.

To learn more about OMOP and find tools and resources to get started with it, visit **Observational Health Data Sciences and Informatics (OHDSI)**.



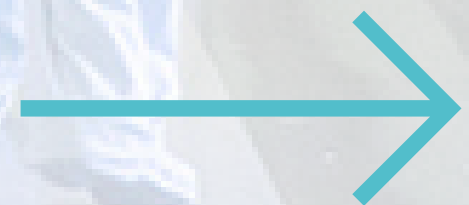


How will my hospital benefit from joining PHDS?



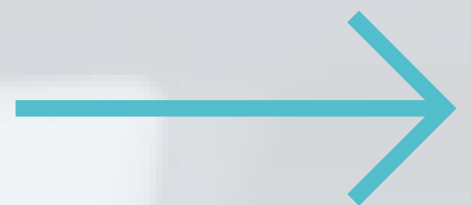
The **Pediatric Health Data Space** will provide multiple **benefits to hospitals** in terms of research and hospital operations.

- ▶ **Benchmarking:** Participate in existing benchmarking initiatives or design new ones based on your hospital's needs. Compared to current multi-center benchmarking efforts, benchmarking in the PHDS will be **automated and require less manual data entry**.
- ▶ **Clinical trials:** Speed the assessment of clinical trials that can be performed in your hospital.
- ▶ **Rare Diseases Research:** Increase the capacity for your staff to conduct research in areas with small number of patients, like rare diseases.
- ▶ **Machine Learning and AI:** Application of AI and machine learning due to increased number of patients and use of synthetic data.



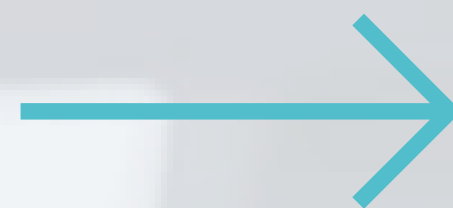


How does the PHDS relate to DARWIN EU?



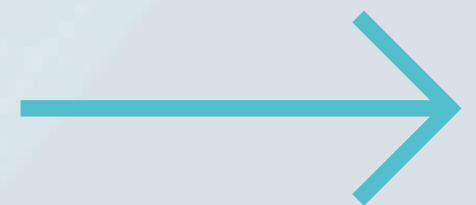
The **Data Analysis and Real World Interrogation Network (DARWIN EU®)** provides **real-world evidence from across Europe diseases, populations and the uses and performance of medicines** to the European Medicines Agency (EMA) and other regulatory bodies in Europe.

Both the **PHDS and DARWIN EU use OMOP Common data language model**, making the PHDS compatible with DARWIN EU. Once the PHDS is fully operational, the **PHDS could potentially apply to be a data provider for DARWIN EU**, increasing the ability of EMA to conduct pediatric studies.





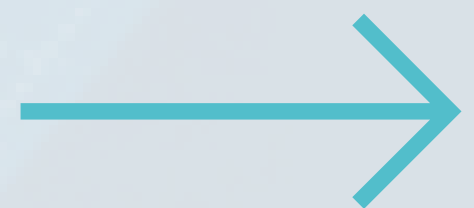
What is the relationship between the Pediatric Health Data Space (PHDS) and the European Health Data Space (EHDS)? Do we need both?



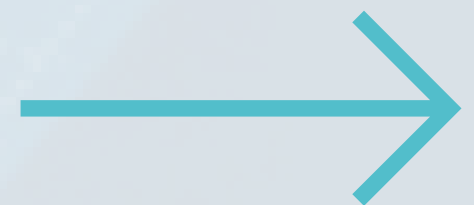
The PHDS is an example of an innovative data access initiative permitted under the EHDS. **The two initiatives are complimentary, not duplicative.**

Importantly, the **PHDS and the EHDS** have the **same overall objective:**

- ▶ **Increase access to secondary health data in a secure and privacy-protecting manner** to accelerate research and improve patient outcomes.



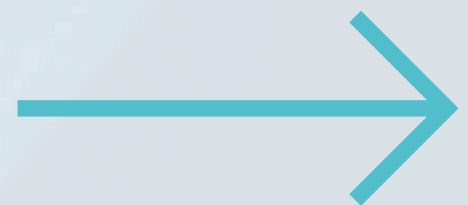
- ▶ **Data movement:** The EHDS pools individual records in a Secure Processing Environment. In contrast, the **PHDS uses a federated network**, so individual patient records stay in the hospital and only aggregated results are pooled in a Secure Workspace.
- ▶ **Timeline:** The EHDS will make secondary data available in early 2029, whereas the **PHDS aims to launch in late 2026 or early 2027.**



Another distinguishing factor of the PHDS is that it will **utilize synthetic data to support machine learning and model testing.**

Any work done **harmonizing data for the PHDS can also be applied to the EHDS**, so there is no duplication of effort in participating in the PHDS.

To learn more about the similarities and differences between the EHDS and PHDS, **go to our Meet-Up on YouTube.**





How is data privacy managed in the PHDS?

In the **PHDS**:

- ▶ **Patient data never leaves the hospital**, so it is subject to the same privacy and security measures that a patient's hospital has in place.
- ▶ **Compliant with all national and European laws on patient privacy.** It is privacy-preserving by design.

Follow and visit **PHEMS** for
more FAQs !

<https://phems.eu/>