

Governance, Data Access and Quality Framework

Hope for children Pediatric Oncology and Hematology Registry

1. Introduction

The *Hope for children Pediatric Oncology and Hematology Registry* is a national clinical data infrastructure collecting information on children diagnosed with cancer and hematological malignancies and treated in specialized Pediatric Oncology and Hematology Clinics in Poland.

The registry aims to support epidemiological analyses, clinical research, and quality monitoring of pediatric oncology care. By enabling standardized data collection across participating clinics, the registry contributes to improving understanding of disease patterns, treatment outcomes, and long-term effects of therapy.

The registry collects longitudinal clinical data covering diagnosis, treatment, outcomes, and follow-up information.

2. Governance structure

The governance of the registry is based on collaboration between a scientific society responsible for data stewardship and a non-profit organization responsible for the technical and operational management of the system.

Data holder

Polish Society of Pediatric Oncology and Hematology (PTOHD)

PTOHD provides scientific oversight of the registry and acts as the data holder. The society is responsible for the overall governance of the data source, including supervision of registry use for research purposes and ensuring that data processing complies with applicable legal and ethical requirements.

Technical and organisational administrator

Saving Kids with Cancer Foundation (SKCF)

The Saving Kids with Cancer Foundation serves as the technical and organisational administrator of the registry. The Foundation provides the technical infrastructure, supports system development and maintenance, and coordinates operational activities related to registry management.

The Foundation also coordinates the national Data Managers Network supporting data collection in participating clinics.

3. Participating institutions and data capture

Clinical data are collected in specialized Pediatric Oncology and Hematology Clinics participating in the registry network.

Data entry is performed by trained clinical personnel and supported by data managers working within participating clinics. Data are recorded through a secure web-based registry system designed for structured clinical data capture.

The registry collects longitudinal patient records including information related to:

- diagnosis and disease characteristics
- treatment protocols and therapeutic interventions
- clinical outcomes
- follow-up information and long-term outcomes where available

Standardized variables and structured data entry forms are used to ensure comparability of information across participating institutions.

4. Data management and system infrastructure

The registry operates through a secure information system designed for clinical data management. The system supports standardized data entry, controlled user access and monitoring of data quality.

Access to the system is restricted to authorized users who receive individual user accounts and role-based permissions. User activity within the system is logged and monitored.

The Saving Kids with Cancer Foundation provides technical support for system users and maintains the technical infrastructure necessary for registry operation.

5. Data access and use for research

Access to registry data for research purposes is subject to controlled procedures.

Researchers interested in using registry data must submit a research proposal describing the scientific objectives, methodology and scope of requested data. Requests are reviewed within the registry governance framework.

Access to data may require additional approvals depending on the nature of the study and applicable ethical or legal requirements.

Data provided for research purposes may be aggregated, anonymized or pseudonymized depending on the study design and applicable regulations.

The registry supports scientific research aimed at improving understanding of pediatric cancers and hematological diseases, treatment outcomes and long-term survivorship.

6. Data quality assurance and validation

Data quality is supported through several mechanisms integrated into the registry workflow.

These include:

- standardized clinical variables and data entry forms
- consistency checks during data entry
- ongoing monitoring of data completeness and quality
- training and support for data managers involved in data collection

The national Data Managers Network plays an important role in supporting consistent data collection practices across participating clinics.