Frankfurt Exercise and Nutritional Therapy Registry in Pediatric Oncology: Study Protocol

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BACKGROUND

- Real-world data essential to understand treatment delivery in routine care, identify care gaps, and evaluate outcomes beyond controlled clinical trials [1]
- Currently, no national or international registry systematically captures exercise and nutrition therapy data in pediatric oncology care [2, 3]

OBJECTIVE

to establish a local, quality registry to systematically collect routine data on therapy delivery and outcomes related to physical and nutritional status in children, adolescents, and young adults with cancer.

METHODS

- **Monocentric observational** registry at the Department of Pediatrics, University Hospital Frankfurt
- Inclusion of **infants**, **children**, **adolescents, and young adults** with a diagnosis of childhood cancer receiving exercise and/or nutrition therapy at the Frankfurt site as per standard operating procedure
  - **Exercise-related data**: age > 3 yrs + medical clearance to participate in exercise
  - **Nutrition-related data**: no age restriction with medical clearance to participate n nutritional counselling
- Exclusion from prospective data collection with no consent to participate in study

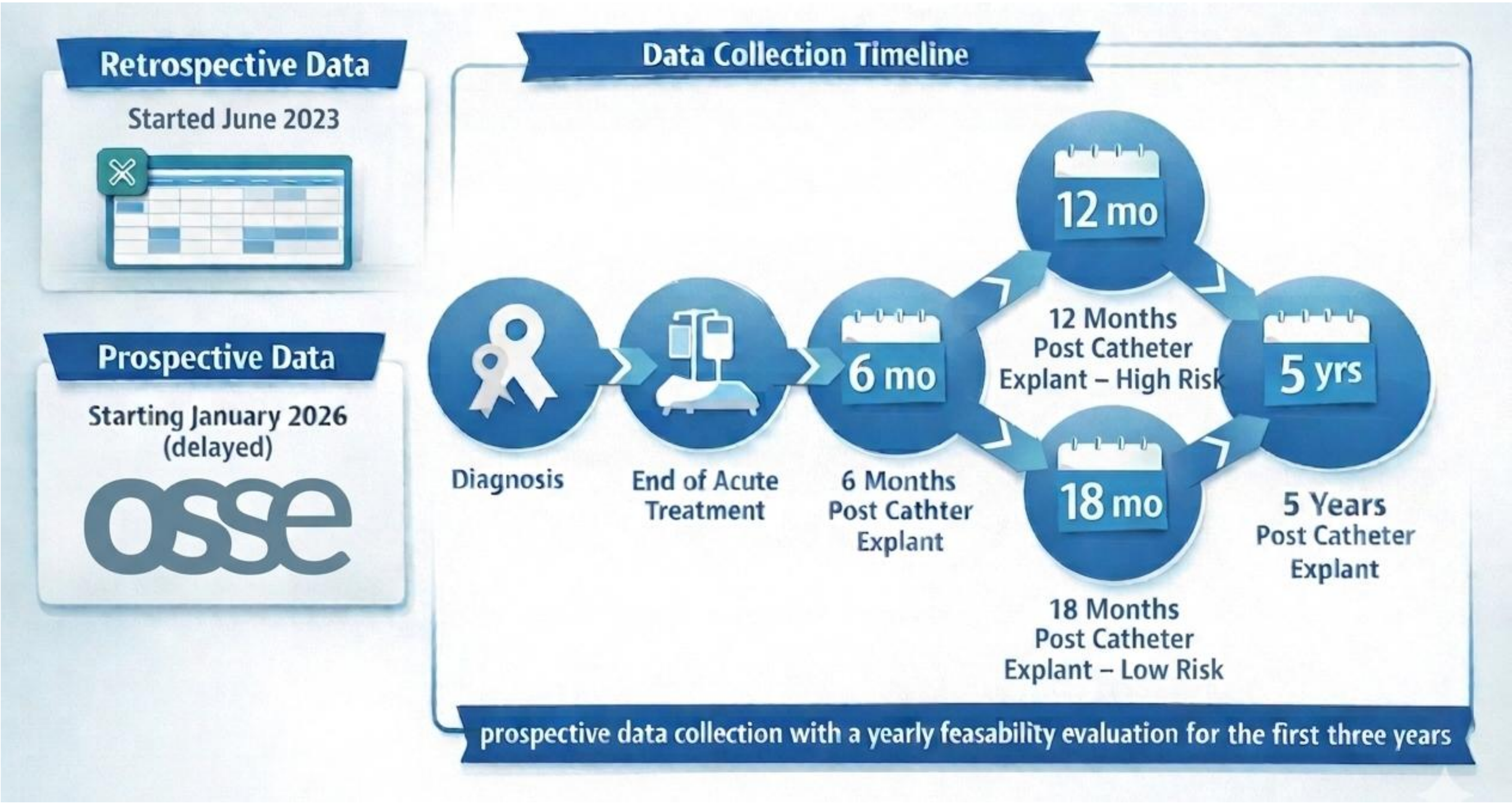

FIG. 1: PROTOCOL OF DATA COLLECTION (AUTHOR'S OWN ILLUSTRATION, CREATED WITH GENSPARK)

FIG. 2: OVERVIEW OF DATA STRUCTURE WITH EXEMPLARY DATA ELEMENTS, AND RESPECTIVE SOURCES (AUTHOR'S OWN ILLUSTRATION, CREATED WITH GENSPARK)

OPPORTUNITIES

- Improve transparency of **care trajectories** and quality of supportive care specific to tumor types, age groups, and treatment intensities based on real world evidence
- Estimate **prevalence** of malnutrition and physical deconditioning
- Explore **risk and protective factors** for malnutrition and physical inactivity
- Explore **interplay** between nutritional and exercise therapy intervention
- Evaluate **guideline adherence** and identify **quality indicators** for supportive care
- **Share** data with patients and enable multicenter collaboration

CHALLENGES

- Align with **clinical workflows** and routine therapy documentation
- Multicenter registry/ Likage: **Interoperability**, data standardisation, minimal data set
- No **patients were involved** in the protocol development
- Funding and **long-term operation**
- IT: data **interface** with HIS
- Ensure **data quality**, check continuously for plausibility
- Consider and report large **RCTs** in the field
- Achieving high patient participation and **manage consent** carefully

NEXT STEPS

- Set up register software **OSSE** (Open Source Registry System for Rare Diseases)
- Test feasibility with **dummy data**
- **Minimise** data
- Submit ethics application and **register** protocol
- Refine **data management plan**
- Manage **change** and de-implement current documentation processes in place
- Evaluate **feasibility metrics** (i.e. documentation time, participation rates, and data completeness)
- **Optimize** registry structure, data standardization, data collection processes and technical interoperability

REFERENCES

[1] Gliklich RE et al. Registries for Evaluating Patient Outcomes: A User's Guide. 4th ed. AHRQ Publication No. 19(20)-EHC020. Rockville, MD: Agency for Healthcare Research and Quality; September 2020.. DOI: https://doi.org/10.23970/AHRQEPCREGISTRIES4.

[2] Institut für Qualität und Patientensicherheit (2026). Registerdatenbank der medizinischen Register in Deutschland. Available at https://registersuche.bqs.de/search.php

[3] European Network of Cancer Registries (2026). Available at https://www.encr.eu/

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