EUROPEAN UNION

MONALISA

A SIOPEN pragmatic clinical trial to MOnitor NeuroblastomA relapse with LIquid biopsy Sensitive Analysis



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5 years Cancer Mission:
Stronger Through Connection

BRUSSELS
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St. Anna Kinderkrebsforschung
CHILDREN'S CANCER RESEARCH INSTITUTE

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What is Neuroblastoma?

Clinical challenge in paediatric cancer

- **Most common extracranial solid tumour in young children / toddlers**
  - 1,500 yearly new cases in the European region
- **Tumour origin at embryonal cells of the sympathetic nervous system**
  - Primary tumours mainly in the adrenal gland
- **Accounts for 15% of death in children with cancer**
- **Very heterogenous clinical and biological course**
  - High-risk disease (50% patients):
    - Specific genetic alterations
    - Metastasized (>90% to bone marrow)
    - 5-year survival rate below 50%

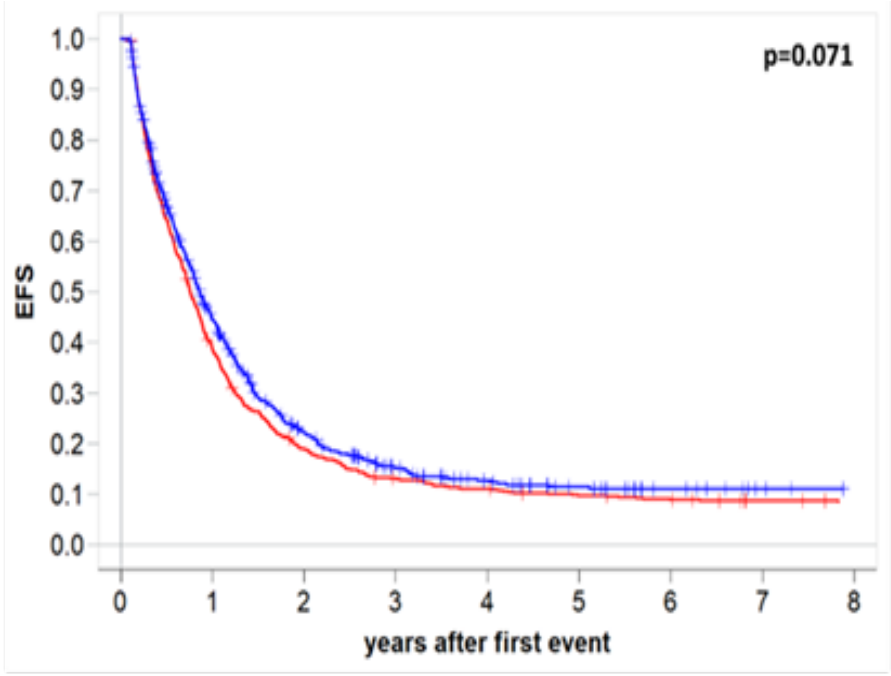


What is Neuroblastoma?

Clinical challenge in paediatric cancer

- **>60% of patients with high-risk neuroblastoma have a relapse within the 1st year after treatment completion**
- **<10% of patients with a relapse or progression can be cured**
- **Intensive multimodal treatment over ~1.5 years**
  - chemotherapy, radiotherapy, immunotherapy

Event-free survival of neuroblastoma patients with first relapse



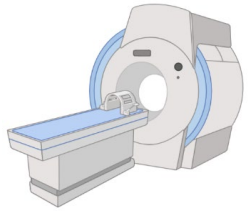
	Events/Patients	1-yrs EFS	2-yrs. EFS	3-yrs. EFS	5-yrs. EFS
Before 2012	594/653	0.39±0.02	0.19±0.02	0.13±0.01	0.10±0.01
2012 or later	553/660	0.44±0.02	0.22±0.02	0.15±0.02	0.11±0.01

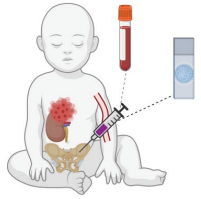


Neuroblastoma disease monitoring

A clinical and patient unmet need

- **Response evaluation and follow-up monitoring according to international standards**
  - Imaging: MRI, MIBG-scan
  - Bone marrow assessment
  - Every 3-6 months – invasive and burdensome





- **We need better and less invasive markers: Liquid biopsies**
  - Frequent sampling of peripheral blood samples with sensitive detection of tumor markers
  - qPCR for NB mRNA detection
  - cfDNA-based assays (NGS, ddPCR)
    - Early relapse detection
    - Detection of therapeutic targets





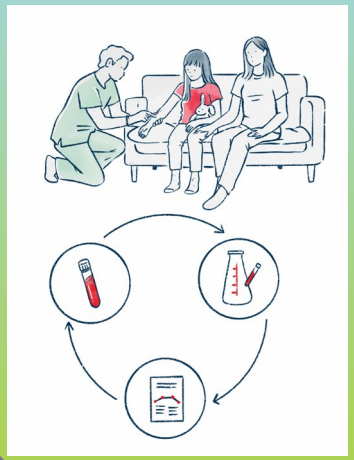
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MONALISA (2024-2028)

First trial prospectively evaluating liquid biopsies in paediatric cancer and to base clinical decision making on liquid biopsies

AIMS



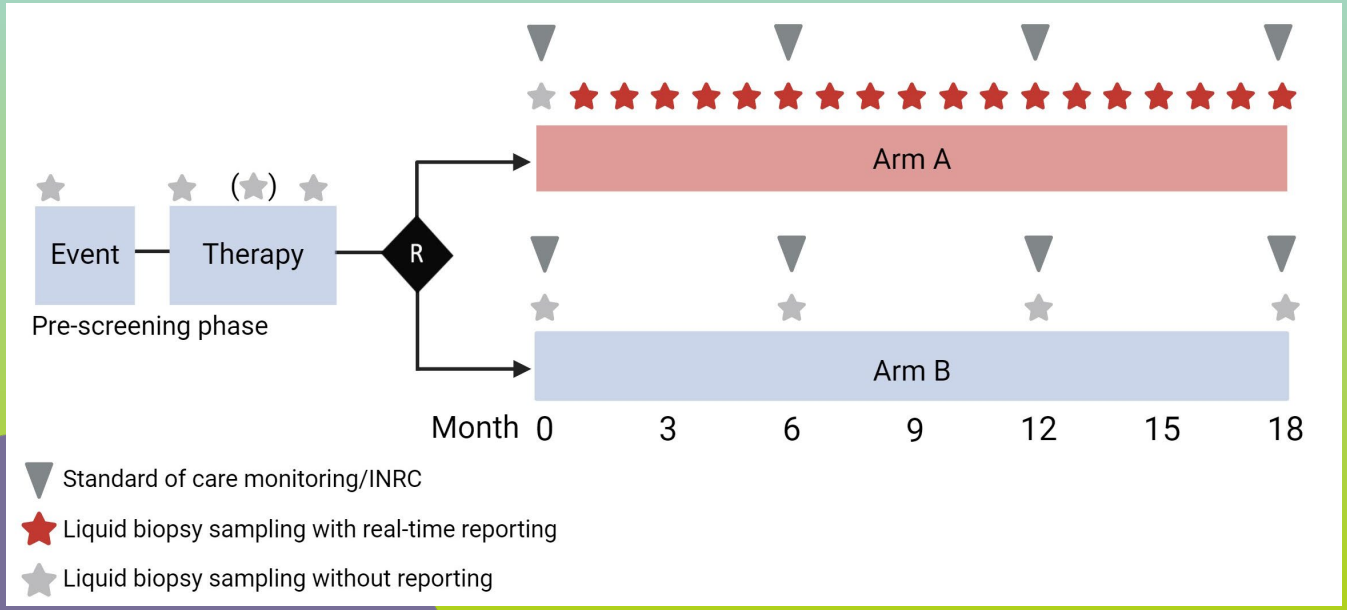
- Establish a pragmatic randomized clinical trial for patients with relapsed neuroblastoma to test in real-time if liquid biopsies can detect a relapse earlier
- Support trial by building a historical cohort (analysis of retrospective studies)
- Develop (links to) databases and a digital decision support tool to help oncologists use data from the liquid biopsy monitoring
- Assess patient-reported outcomes and quality of life in MONALISA app

➢ **Long-term objective: To establish liquid biopsies as standard-of-care**

MONALISA Highlights

Opening of MONALISA Clinical Trial, enrolment of first patients and start of real-time liquid biopsy testing in reference laboratories

Aim to randomize 150 patients with relapsed neuroblastoma into 2 trial arms: *standard follow-up* vs. *standard follow-up plus monthly liquid biopsy testing*



MONALISA Highlights



Opening of MONALISA Clinical Trial, enrolment of first patients and start of real-time liquid biopsy testing in reference laboratories

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Liquid biopsy tests according to EU IVDR

- 5ml peripheral blood
- Innovative & sensitive mRNA and cell-free DNA assays
- 7 reference labs > QC/QA + training

- Secure link to databases for future paediatric cancer research (UNCAN, EHDS)
- Established clinical decision support tool
- Patient-reported outcome measures (QoL) with dedicated MONALISA App

MONALISA long-term impact



Establish liquid biopsies as standard-of-care in paediatric cancer monitoring

- Increase acceptance among oncologists, patients and families
- Accelerate digital transformation of research innovation
- Knowledge dissemination
- Reduce healthcare costs

THANK YOU!



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Thanks to all patients and families!

EU Project Coordination



Sabine Taschner-Mandl

St. Anna Kinderkrebsforschung
CHILDREN'S CANCER RESEARCH INSTITUTE

Clinical Trial Sponsor



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pediatric oncology

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Get more information!

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