

# Paediatric clinical trials need paediatric clinical trial budgets

## Stavros Koulizakos

Clinical Research Lead  
Pediatric Clinical Research Center (PCRC)  
Sahlgrenska University Hospital  
Gothenburg, Sweden

## Jenny Kindblom

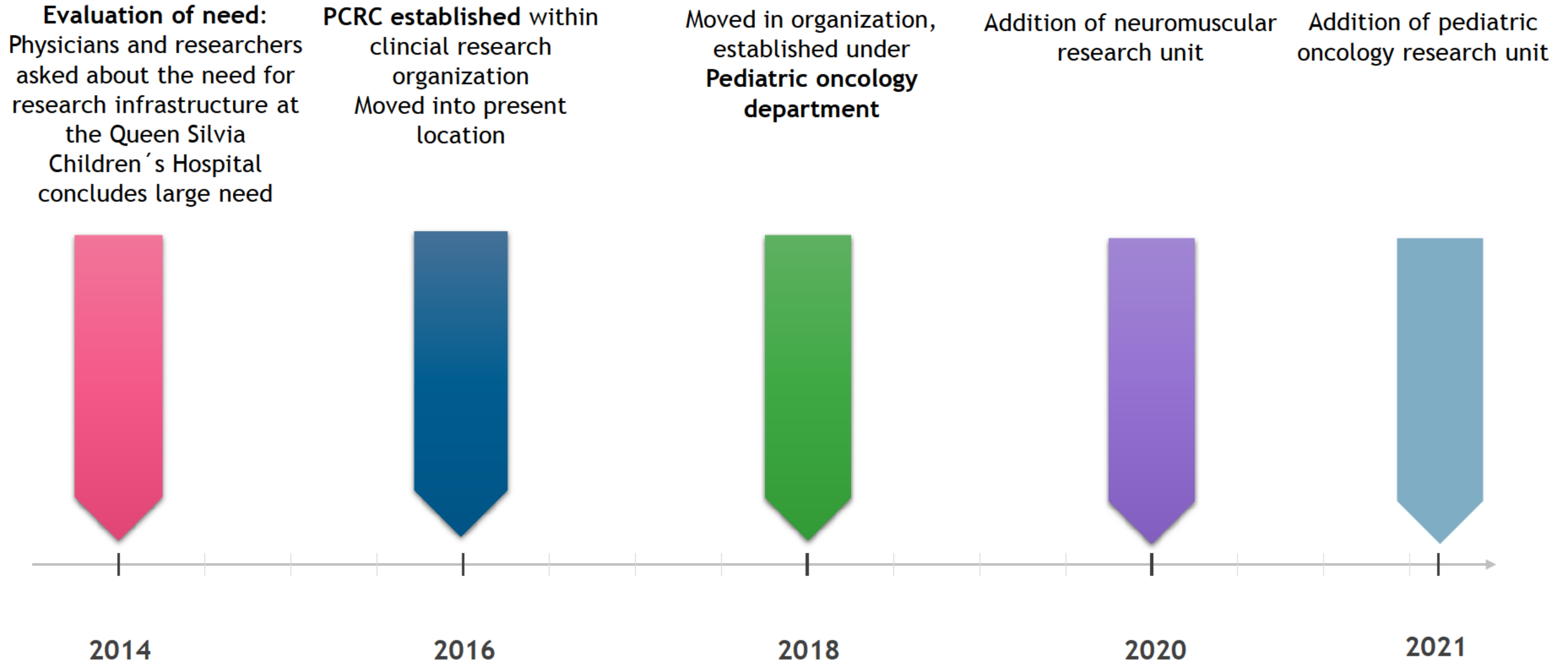
MD, PhD, Senior Consultant Clinical Pharmacology  
Sahlgrenska University Hospital & the Sahlgrenska Academy  
Gothenburg, Sweden



No disclosures



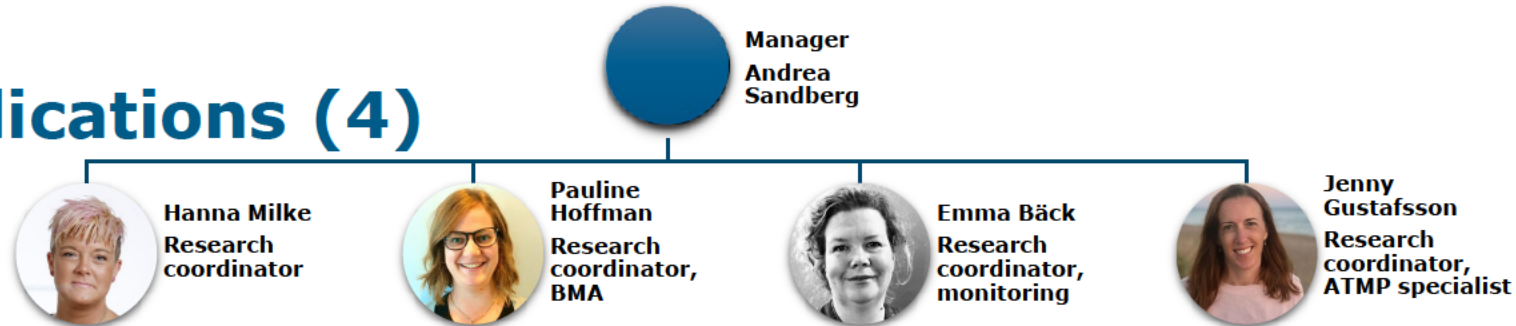
# Background Pediatric Clinical Research Center (PCRC)



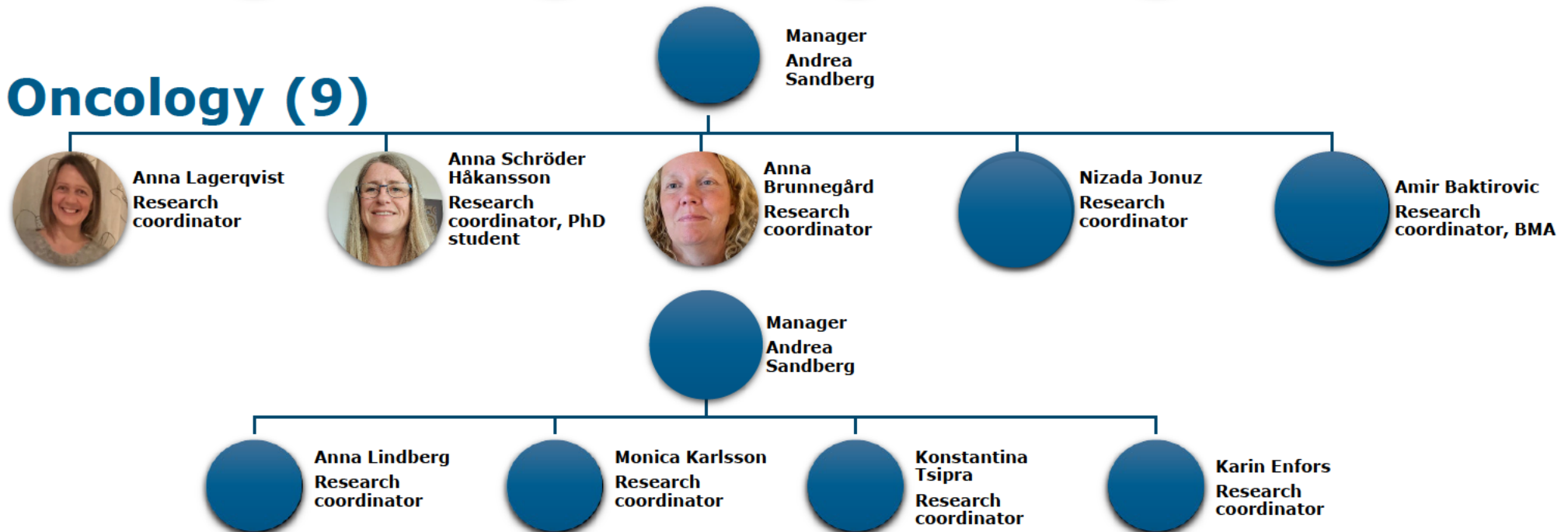
# Multiprofessional Team



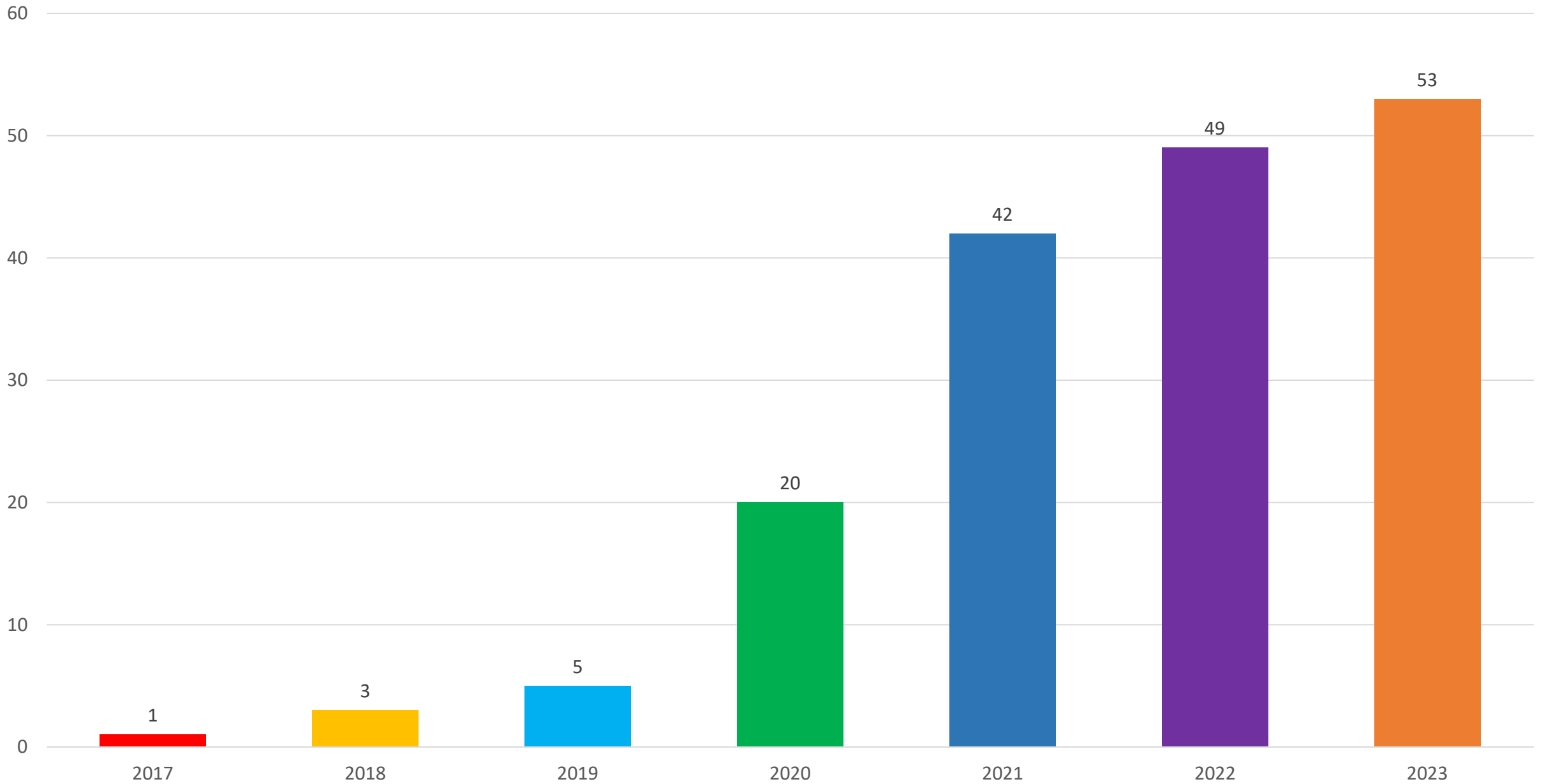
## All Indications (4)



## Oncology (9)



## Number of pediatric drug trials



# Clinical Trials in Children

Lack of Paediatric Label

Need for new treatments

Need for Clinical trials in Paediatrics

# AIM

To describe experiences with budget preparations  
in paediatric clinical trials



# METHODS

- Selected 10 trials sponsored by the pharmaceutical industry.
- Compared the sponsor's initial budget with the final budget.
- Used mean and range to characterise the difference (%) in total budget amount between the initial and final budget.





# RESULTS

- Mean total amounts:  
+59% (range 31%–139%)
- Average difference in start-up costs:  
+84%, range up to +175%



## Start-up Costs

Budget preparation, contracts, internal agreements, applications to authorities and preparation of study visits



## Study Activities Costs

Informed consent, physical examination, Physiotherapeutic tests, blood samples, administration of IMP

## Examinations

Gastro/Colono/Sigmoidoscopy, MRI, CT-Scan, ECHO, Biopsy



# Conclusion

- A substantial part of the trial-related costs would not be covered by the sponsor, if the initial budget had been accepted
- Review the budget, analyse the Site trial costs with the assistance of The PI's & SC's and negotiate!

Received: 5 March 2023 | Revised: 25 April 2023 | Accepted: 27 April 2023

DOI: 10.1111/apa.16808

ORIGINAL ARTICLE

ACTA PÆDIATRICA  
NURTURING THE CHILD  
WILEY

## Paediatric clinical trials need paediatric clinical trial budgets

Stavros Koulizakos<sup>1</sup> | Tina Kjellén<sup>1</sup> | Karin Mellgren<sup>2</sup> | Jenny M. Kindblom<sup>1,3</sup> 



# Acknowledgements

Tina Kjellén, Karin Mellgren

Pediatric Clinical Research Center (PCRC)

Children's Cancer Center, Queen Silvia Children's Hospital

Sahlgrenska University Hospital







REGION  
VÄSTRA GÖTALAND  
SAHLGRENSKA UNIVERSITY HOSPITAL