Paediatric clinical trials need paediatric clinical trial budgets

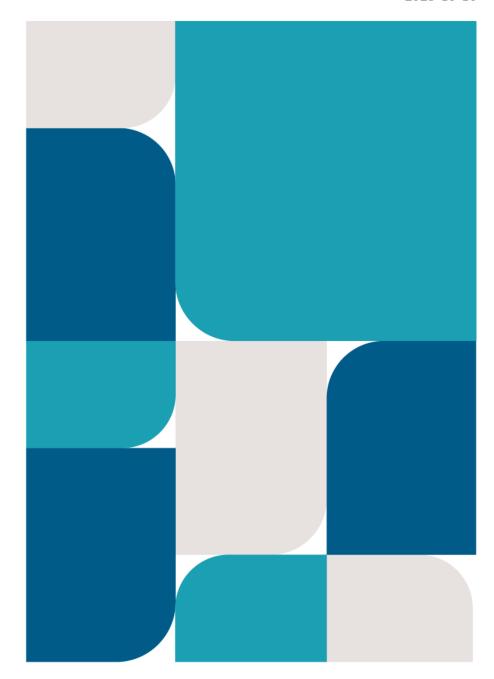
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No disclosures

Background Pediatric Clinical Research Center (PCRC)

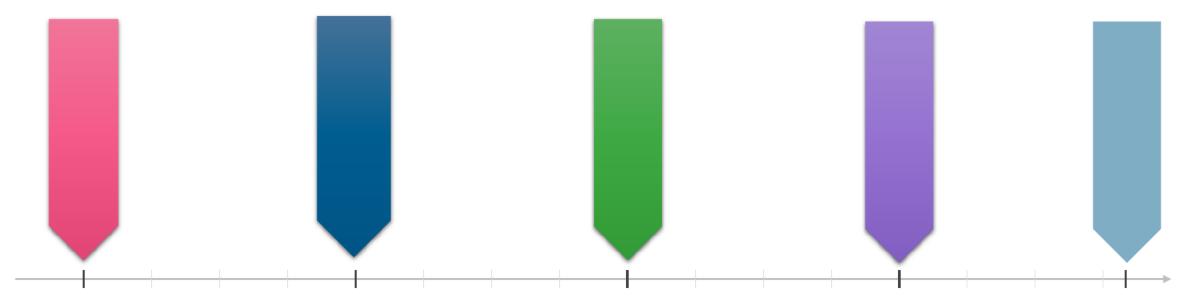
Evaluation of need:
Physicians and researchers asked about the need for research infrastructure at the Queen Silvia
Children's Hospital concludes large need

PCRC established within clincial research organization
Moved into present location

Moved in organization, established under Pediatric oncology department

Addition of neuromuscular research unit

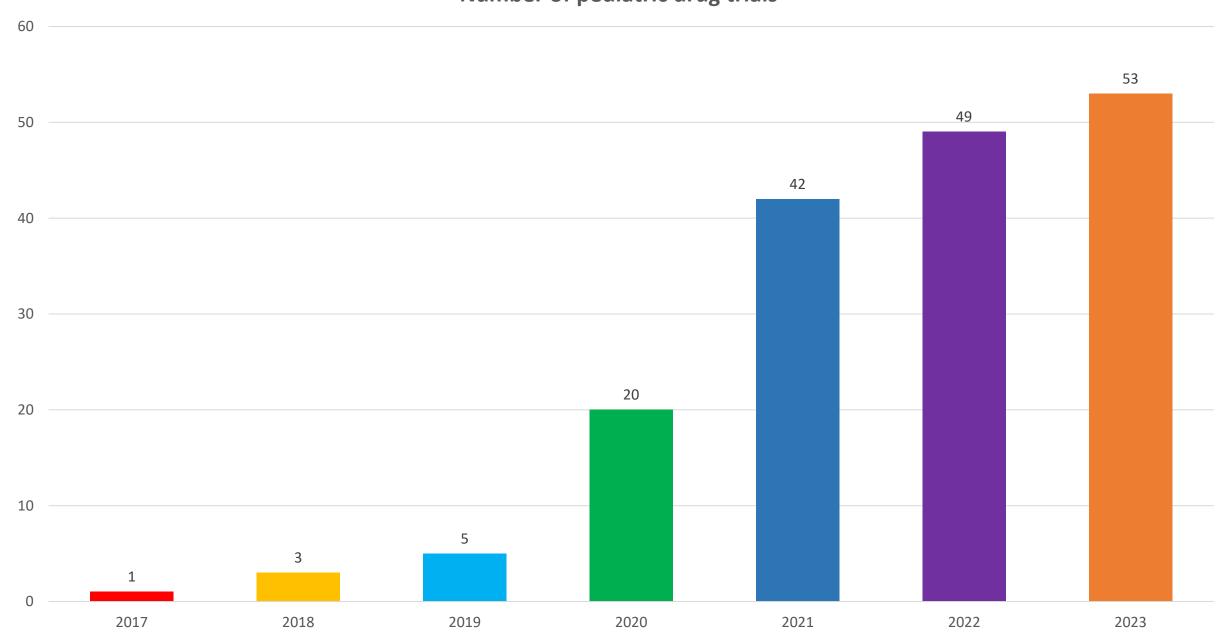
Addition of pediatric oncology research unit



2014 2016 2018 2020 2021

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Number of pediatric drug trials



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Clinical Trials in Children

Lack of Paediatric Label

Need for new treatments

Need for Clinical trials in Paediatrics

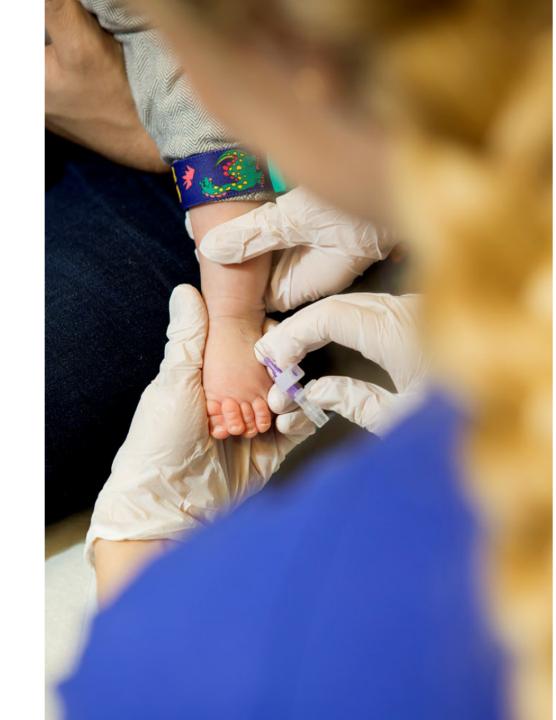
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AIM

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!

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ORIGINAL ARTICLE



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