How to organize a paediatric Clinical Trials Unit

4th Nordic Conference on Paediatric Medicines

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Limitations

PBM, not EBM

Conflict of interest: Tampere University and Tampere University Hospital – employee Roche, Boehringer-Ingelheim, Injeq – Advisory board Multiple pharma companies – PI or SI in different clinical trials
What the talk is about?

From the idea to practice
What have we learned
PeeTU – Clinical Trials Unit
→ a brief introduction
Clinical trials at the Children’s Hospital in Tampere in 2016:
From then to now

PeeTU in numbers

- Trials open: 0, 7, 12, 16, 17, 14, 0
- Patients: 0, 17, 19, 31, 27, 36
- Physicians involved: 3, 7, 8, 24, 33
- Visits: 17, 39, 75, 111, 129

Colors represent years 2016-2021.
Organizing a CTU - planning

What are we aiming for?
- Unmet demand?

Who is in the target population?

What is already in place, what needs to be improved?

Resourcing
Challenge: Children are healthy
Children first

Drugs administered to children with cancer were typically developed under the assumption that childhood cancers are similar to their tissue-matched adult counterparts. Focusing on identifying and targeting alterations present specifically in childhood tumors will accelerate the development of tailored therapies and improve the prognosis of children with cancer.

* Everyone of us has been a child – yet only few of us remember it!
* Kids are not small adults
* Children deserve more than an estimate!
More pediatric clinical trials, but how?

PeeTU
Why Finland for pharmaceutical R&D?
Land of a Thousand Possibilities
Tampere University Hospital – the heart of pediatric research in Finland

- FONK – Phase I/II Oncological Trial Unit founded in 2015
  - 30–40 Phase I – III trials conducted per year
- PeeTU – Pediatric Early Phase Trials Unit.
  - Member of ITCC
PEDIATRIC CLINICAL TRIALS UNIT IN TAMPERE UNIVERSITY HOSPITAL

Welcome to the Pediatric Clinical Trials Unit – the PeeTU.

We provide expertise, infrastructure and resources to conduct clinical trials (phase I-III) for children across pediatric subspecialities in Finland.

TAMPERE UNIVERSITY HOSPITAL

- 11 trained nurses for pediatric clinical trials
- Research and Clinical trials Service Unit with administrative support and services
- Patient hotel Norlandia Tampere Hotel in the hospital campus
- The new Children’s Hospital with state-of-the-art facilities
- Organised biopanking activity within the hospital (Tampere Biobank)

Child population by buffer in the area of Tampere University Hospital

- 150 200 children in 0-100 km
- 703 400 children in 0-170 km
- 828 200 children in 0-250 km

Tampere University Hospital (Tays)

Total population of Finland:
5 503 300

1.2 million
Children in Finland
PeeTU today

• Planning in 2016
• Established 2017
• Investigator(s)
• Study nurse(s)
• A pool of pediatric nurses trained
• Training for doctors in training
• ”Protected time”
Trials in different fields of pediatrics

- Infectious diseases
- Immunology
- Nephrology
- Cardiology
- Gastroenterology
- Hematology
- Oncology
- Rheumatology
- Neonatology
- Pulmonary Medicine
- Endocrinology
- Neurology
The way we work

Trial proposal

• Evaluated by director & study coordinator \(\rightarrow\) is the trial feasible?
• If feasible, contacting specialists: is there a need for this, do we have patients

If yes \(\rightarrow\) green light for further evaluation

Flexible
How things can change – we need flexibility

Original Research

Impact of COVID-19 in paediatric early-phase cancer clinical trials in Europe: A report from the Innovative Therapies for Children with Cancer (ITCC) consortium
Benefit

- New drugs earlier
- Close
- Humane – oncology patients
- Improving therapies
- Teaching and learning
Networking

ITCC (Innovative Therapies for Children with Cancer)

- European consortium
- NOPHOmatch*
  Copenhagen, Göteborg, Oslo, Tampere, Stockholm ITCC
Expansion of scope
Health and wellbeing from the womb to adulthood

Pregnancy
Foetus in the womb
Baby / Infant (birth - 1 year)
Toddler (1 - 3 years)
Preschooler (3 - 5 years)
Primary School Boy (5 - 12 years)
Adolescent / Teenager (13 - 19 years)
Adult (36 - 55 years)
Old Person (65+ years)

Tampere Center for Child, Adolescent, and Maternal Health Research (TamCAM)
Is it ethical to conduct clinical trials in children?

Is it ethical not to?