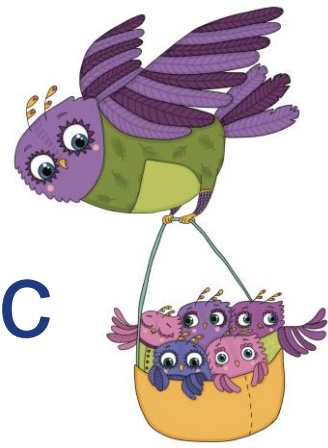


# How to organize a paediatric Clinical Trials Unit



*4th Nordic Conference on Paediatric Medicines*

Sauli Palmu, MD, PhD





# 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

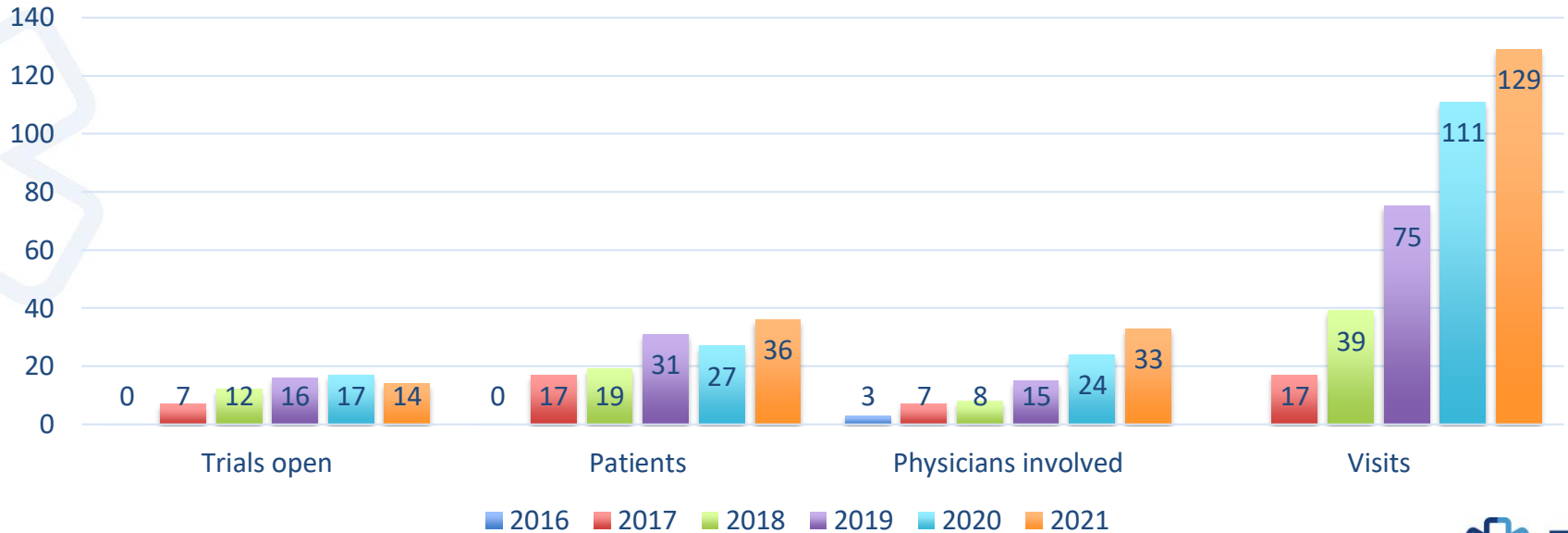


# Clinical trials at the Children's Hospital in Tampere in 2016:



# From then to now

## PeeTU in numbers



# 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 subspecialties 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 biobanking activity within the hospital (Tampere Biobank)



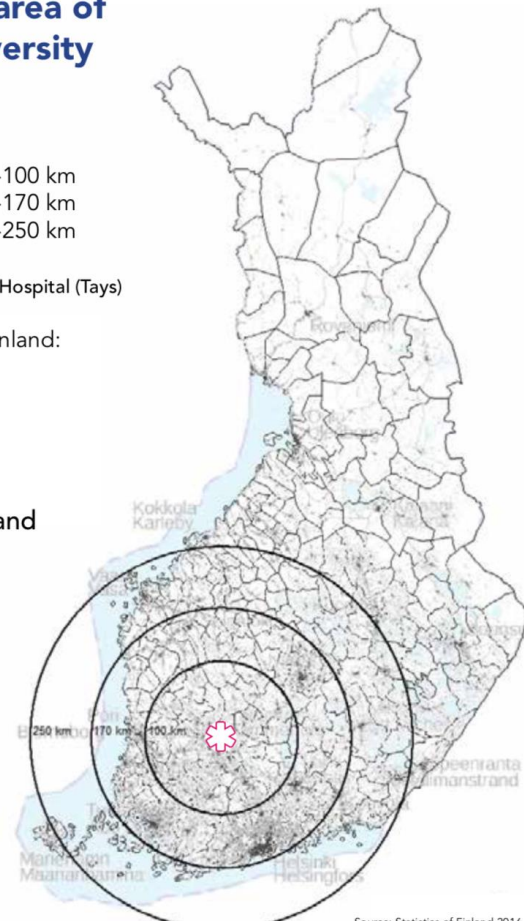
## Child population by buffer in the area of Tampere University Hospital

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 → is the trial feasible?
- If feasible, contacting specialists: is there a need for this, do we have patients

If yes → green light for further evaluation

Flexible



# How things can change – we need flexibility

European Journal of Cancer 141 (2020) 82–91



Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

ScienceDirect

journal homepage: [www.ejancer.com](http://www.ejancer.com)



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

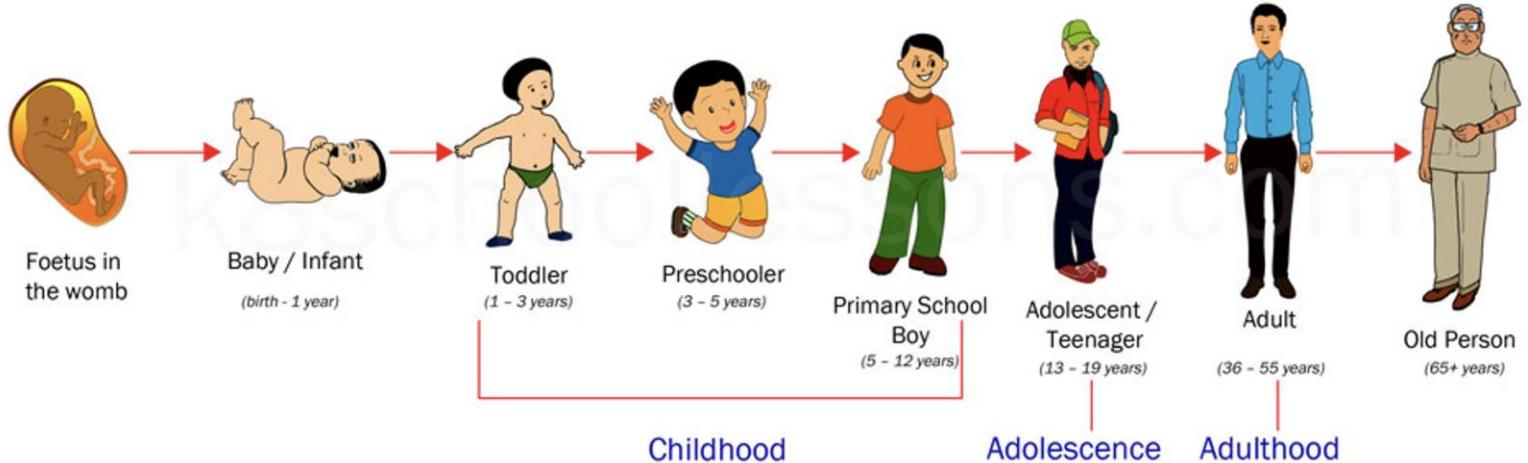




# Expansion of scope Health and wellbeing from the womb to adulthood



Pregnancy



Tampere Center for Child, Adolescent,  
and Maternal Health Research (TamCAM)





# Is it ethical to conduct clinical trials in children?

Is it ethical not to?

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