



HUS⁺

ITCC IN THE NORDIC COUNTRIES – THE FINNISH PERSPECTIVE

Katja Eloranta

PhD, Senior Planning Officer of Pediatric Clinical Trial Unit

Minna Koskenvuo

MD PhD, Associate Chief Physician in Ped Hematology and Oncology, ITCC representative

Virve Pentikäinen

MD PhD, Clinical Trial Unit Physician, ITCC representative

Division of Pediatric Hematology-Oncology, Helsinki University Hospital

4th Nordic Conference on Paediatric Medicines 14.09.2022



Innovative Therapies for Children with Cancer in Europe

The Innovative Therapies for Children with Cancer (ITCC) Consortium was created in 2003. It is a non profit organisation under the French Law.

ITCC gathers 63 European Paediatric Oncology Departments with expertise in conducting early phase trials in children and adolescents, and 25 European research laboratories.

The aim of this organisation is to develop novel therapies for the treatment of paediatric and adolescent cancers in cooperation with regulatory bodies, pharmaceutical enterprises, parents and patients.

In January 2011 ITCC was established as a European Category 1 Network for Paediatric Research at the European Medicines Agency ([EnprEMA](#)).

ORGANISATION





63 institutions and
25 research laboratories
In 16 European countries
and Israel

Finland:

- Tampere University Hospital
- Helsinki University Hospital



Gilles Vassal Feb 16/2022

ITCC ACCREDITATION

- Each prospective ITCC center has to apply for ITCC accreditation.
- The purpose of the accreditation is to ensure applicant´s:
 - Compliance with GCP guidelines
 - Adequate facilities and resources to conduct phase I/II studies
 - Establishment as a moderate/large paediatric oncology centres treating patients in Phase III international collaborative trials.
- ITCC expects a minimum recruitment: each ITCC center should recruit at least one patient for 75% of the ongoing ITCC trials in their center



Strategy

Overarching goal : To accelerate the introduction of new effective and safe therapies in the treatment of children and adolescents with cancer

By means of :

- increasing the likelihood of entering/ **prioritizing potentially effective drugs** in pediatric development **based on science**, increased knowledge of tumor biology and better **preclinical evaluation** to address **unmet medical needs**
- **speeding up the initiation of pediatric studies** with regard to development in adults and the development of drugs specific to pediatric malignancies,
- speeding up the **development of combinations**
- speeding up implementation of **new therapies in first line treatments** of high risk diseases in order to increase the probability of curing more children more rapidly.

Gilles Vassal Feb 16/2022



Strategy

Overarching goal : To accelerate the introduction of new effective and safe therapies in the treatment of children and adolescents with cancer

With:

- **An innovative and outstanding scientific and medical research program** that should be both tumor agnostic and disease-oriented, run by the Tumor Committees
- **An effective and coordinated Industry strategy**

Gilles Vassal Feb 16/2022



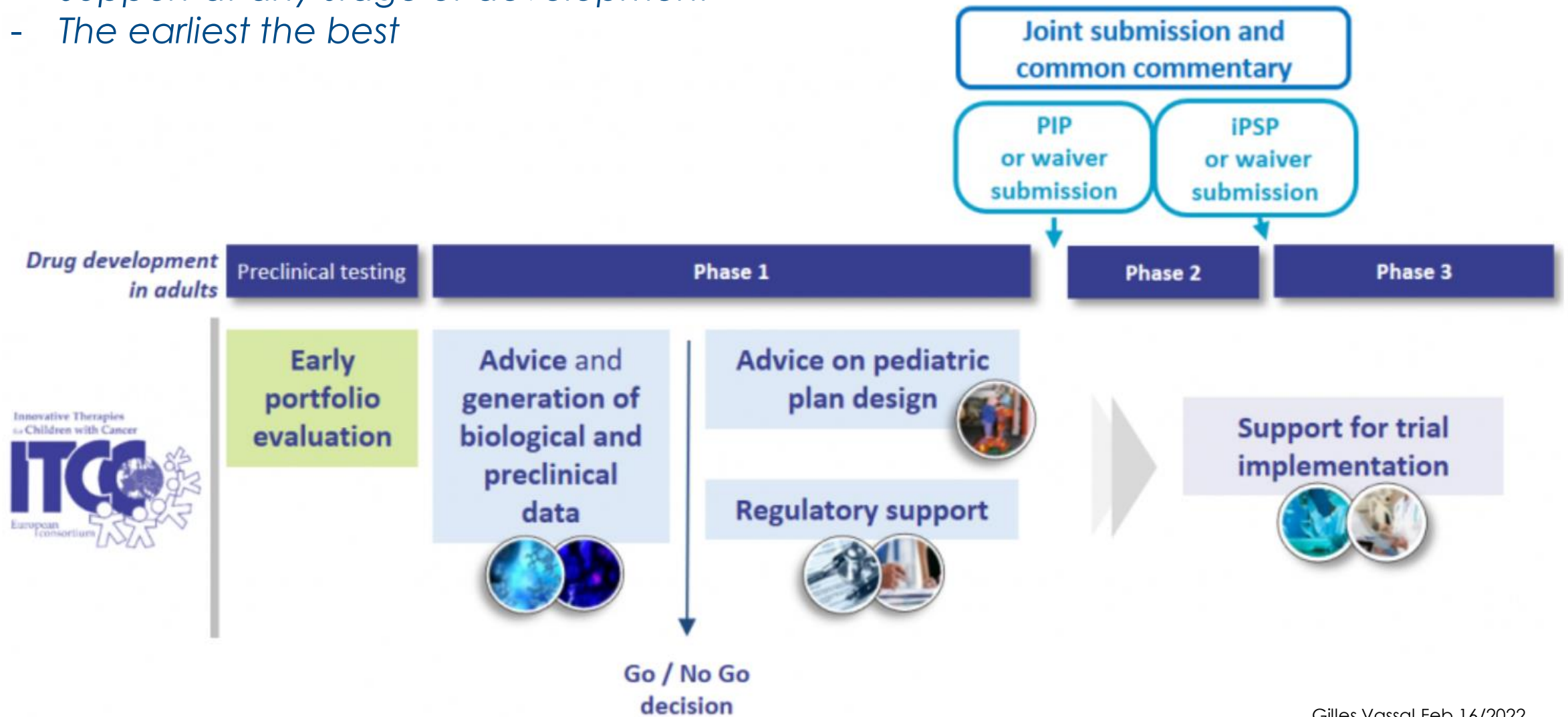
through

- 1. stronger interactions between biological and clinical activities**
- 2. effective cooperation with European tumour groups**
- 3. introduction of new technologies and facilitated access to data, assets and platforms** (integrative analysis, proteomics, liquid biopsies, single cell analysis, organoids,....)
- 4. international cooperation**

Gilles Vassal Feb 16/2022

ITCC strategy to support pediatric clinical trials

- Support at any stage of development
- The earliest the best



Gilles Vassal Feb 16/2022



Industry Strategy

Objectives

- **ensure that industry development programs meet science and patients' needs** by being part of the prioritization processes and discussions,
- **facilitate the implementation of industry trials across the ITCC** network and thus increase the number of ITCC labeled industry trials in Europe
- **facilitate access to compounds for** the development of innovative academic combination trials that will be fit for filing and for basic and translational research conducted within ITCC

Targets : large and medium Pharmaceutical Companies, small biotech and start up companies

Gilles Vassal Feb 16/2022

THE ITCC STRATEGY

EXPERTISE

Biology,
Medicine,
Clinical
research,
Regulatory
science

An efficient
network
of 63 expert
clinical centers
to deliver early
trials

Yearly:

- 1500 relapsed patients
- 20- 25 ongoing early phase trials
- 500-600 patients in trials

A network of
the top 25 EU
research lab on
pediatric
oncology

A sponsor
network of 21
institutions for
rapid
implementation
of IIT and
platform trials

An aggregated
clinical
biological data
base of
pediatric
malignancies
(under construction)

A preclinical
testing platform
with a saturated
repertoire of
pediatric tumor
models
(in development)

Innovative
Technology
platforms for
sequencing,
ctDNA,
single cells,
.....



+ Australia, Canada

Molecular profiling
platforms & database

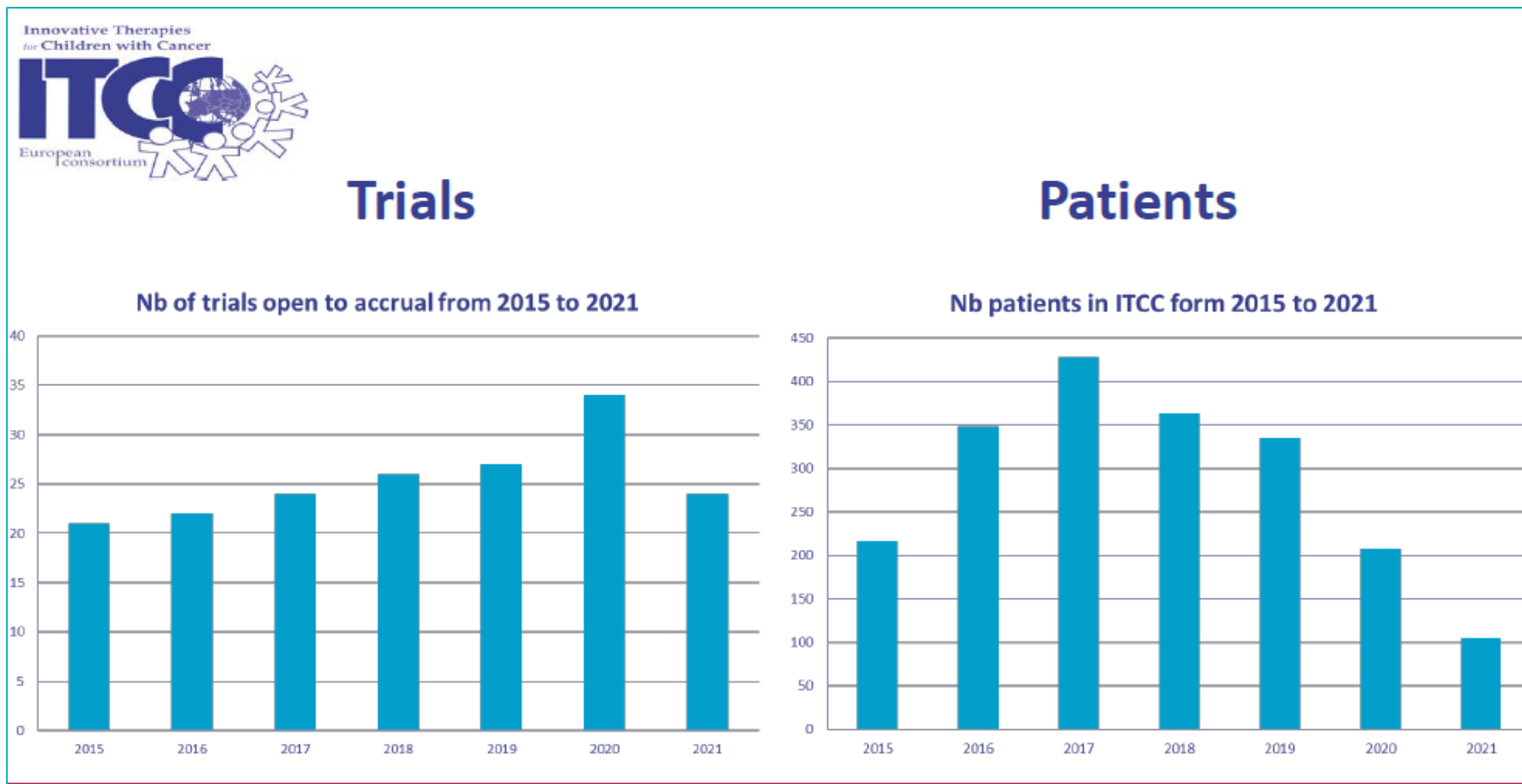
	MAPPYACTS
	INFORM
	I-THER
	SM-PAEDS
	DANISH

ITCC PAEDIATRIC
PRECLINICAL
P4 PROOF OF CONCEPT
PLATFORM

innovative
medicines
initiative
 efpia

Gilles Vassal Feb 16/2022

Improving access of patients to available trials



Gilles Vassal Feb 16/2022

→ *Patient's acces to innovation project*



Patients' Access to Innovation Project

Goal : To characterize the current situation in each ITCC country and to design a project to improve access to innovation towards the ITCC goal

- How access to innovation is organised in the country?
- Are referral patterns established and efficient?
- How access to tumor molecular profiling is set up?
- How to increase patients' access to innovation?

Gilles Vassal Feb 16/2022

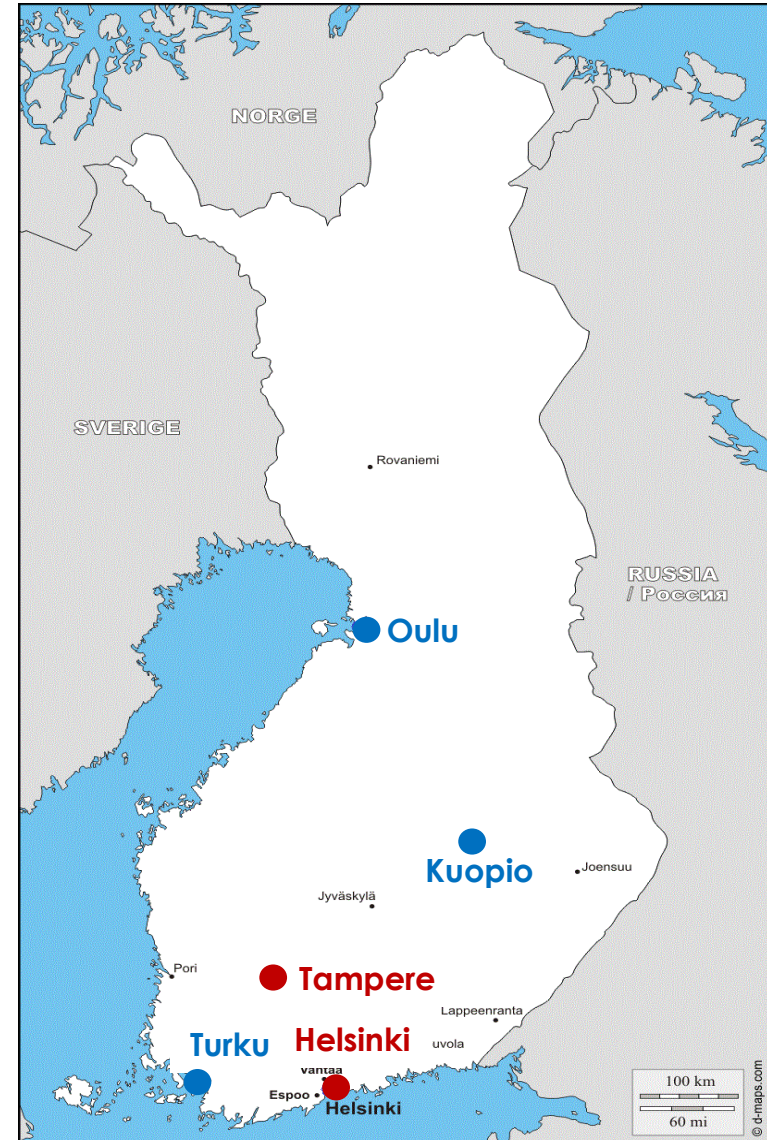
ITCC / FINLAND

Description

- 5 pediatric oncology centers
- 2 ITCC centers
 - Tampere University Hospital
 - Helsinki University Hospital
- 150 new patients/year
- Estimated number of patients in relapse: 30

ITCC activity in Finland 2015 – 2021

- 1 patient enrolled in ITCC trials in Finland (more patients sent abroad to ITCC trials)
- 2 ITCC trials currently opened to accrual in the country in Tampere center



CURRENT PATIENTS' ACCESS TO INNOVATION IN FINLAND

- 2 ITCC centers, frequent information and tumor entity leads
- Proposal from ITCC → the two ITCC centers discuss where to open
- Networking within **NOPHO** (Nordic Society of Paediatric Haematology and Oncology)
 - Updated list of early phase trials on NOPHO website
 - NOPHO Match to discuss difficult cases on demand
 - Easy referral of patients to ITCC centers in other Nordic countries
- Problems:
 - Geographically large country with sparse population
 - Reluctance of Pharma to open trials
 - Off label use is rather easy and paid by hospital following permission

ACCESS TO TUMOR MOLECULAR PROFILING IN FINLAND

- Through national in-house sequencing and Nordic collaboration (methylation analysis in Copenhagen)
- Through INFORM trial now covered by municipal funding in 4/5 centers
- Through iCAN-PEDI project in Helsinki – in-house sequencing funded by research grants and pharma partners towards a platform for all Finnish patients
 - Most patients at relapse have access to molecular profiling

HOW TO INCREASE PATIENTS' ACCESS TO INNOVATION IN FINLAND

- Opening more trials (Helsinki recently started opening ITCC trials)
- Setting up a systematic discussion of patients at relapse
- Sending patients abroad



**Clinical Trial Unit
New Children's Hospital
Helsinki University Hospital**

CTU-HEMA STARTED 2/2021 TO OPEN AND CONDUCT CLINICAL TRIALS IN PEDIATRIC HEMATOLOGY-ONCOLOGY

- Clinical trial unit physician (MD, PhD) (50%)
- Senior planning officer (80%)
- 3 Research nurses (3 x 100%)



HUS CTU-HEMA ONGOING CLINICAL TRIALS 9/2022

Academic sponsor	National PI	
AllTogether1	M. Taskinen/HUS	Recruiting
IntReALL SR 2010	P. Lähteenmäki/TYKS	
IntReALL HR 2010	P. Lähteenmäki/TYKS	Recruiting
NOPHO DBH AML 2012	K. Jahnukainen/HUS	Recruiting, randomization paused
SIOP PNET5 MB	V. Pentikäinen/HUS	Active, not recruiting any more
SIOP Ependymoma II	S. Långström/HUS	Recruiting
LBL 2018	K. Vepsäläinen/KYS	Recruiting
B-NHL2013	P. Huttunen/HUS	Recruiting
rEECur	J. Kanerva/HUS	Recruiting
EsPhALL2017	O. Lohi/TAYS	Recruiting

Commercial sponsor	PI	
CASSIOPEIA (CART f2)	K. Vettenranta/HUS	Recruitment paused
BIANCA (CART f2)	K. Vettenranta/HUS	Recruitment paused
PAVO (CART follow-up)	K. Vettenranta/HUS	

HUS CTU-HEMA UPCOMING CLINICAL TRIALS 2022-2023

Academic sponsor	National PI	Start
ATRT01	S. Långström/HUS	2023
BIOMEDE2.0 ITCC-051	V. Pentikäinen/HUS	2022-2023
SIOP HRMB	V. Pentikäinen/HUS	2022
HRNBL2	M. Koskenvuo/HUS	2023
iEuroEwing	J. Kanerva/HUS	2023
Interfant -21	O. Lohi/TAYS	
IntReALL 2020	S. Ryhänen/HUS	2023
Loggic Core	P. Lähteenmäki/TAYS	2022
PROTEICO	M. Koskenvuo/HUS	2023?
SCRIPT-AML	S. Ryhänen/HUS	2023
YCMB-LR	V. Pentikäinen/HUS	2023
SIOP YCMB-HR	A. Suominen/HUS	2023-2024

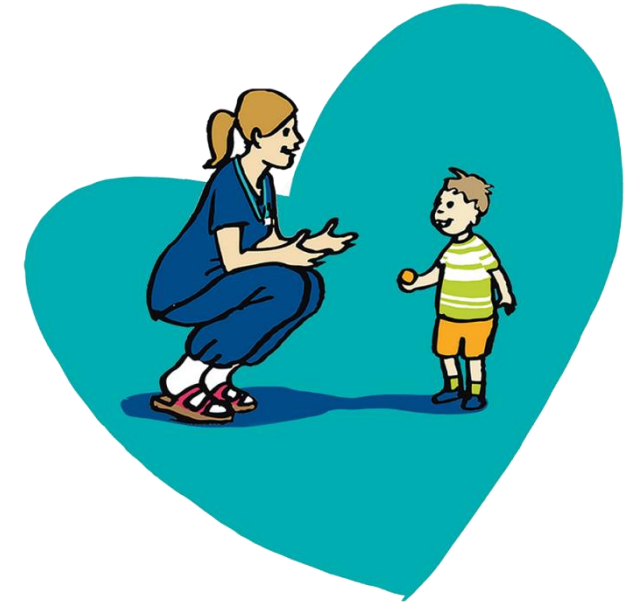
Commercial sponsor	National PI	
ITCC-098 BrigaPED (f1-2)	A. Kyrönlampi/HUS	2022
ITCC-059 (inotutsumab, f1-2)	M. Koskenvuo/HUS	2022
LOGGIC Firefly	K. Nordfors/TAYS	2023
ON-TRK	V. Pentikäinen/HUS	2022
ITCC-01 PedAL (venetoclax, f3,)	P. Huttunen/HUS	2022
Pfizer B1931036 (IntReaLL inotutsumab)	S. Ryhänen/HUS	2023

THANK YOU

Katja Eloranta

PhD, Senior Planning Officer, Pediatric Clinical Trial Unit
Division Pediatric Hematology-Oncology and Stem Cell
Transplantation, Helsinki University Hospital

ped.hema-ctu@hus.fi



**Caring
Pioneers
Equality**