ITCC IN THE NORDIC COUNTRIES – THE FINNISH PERSPECTIVE

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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).
63 institutions and 25 research laboratories in 16 European countries and Israel

**Finland:**
- Tampere University Hospital
- Helsinki University Hospital
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.

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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

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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

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ITCC strategy to support pediatric clinical trials

- Support at any stage of development
- The earliest the best
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
THE ITCC STRATEGY

EXPERTISE
- Biology, Medicine, Clinical research, Regulatory science

An efficient network of 63 expert clinical centers to deliver early 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, ........

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

Molecular profiling platforms & database
- MAPPYACTS
- INFORM
- I-THER
- SM-PAEDS
- DANISH

Australia, Canada

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Improving access of patients to available trials

→ Patient’s access 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?

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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

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<th>Academic sponsor</th>
<th>National PI</th>
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<td>AllTogether1</td>
<td>M. Taskinen/HUS</td>
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<td>IntReALL SR 2010</td>
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<td>Recruiting, randomization paused</td>
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<td>SIOP PNET5 MB</td>
<td>V. Pentikäinen/HUS</td>
<td>Active, not recruiting any more</td>
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<td>BIANCA (CART f2)</td>
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# HUS CTU-HEMA UPCOMING CLINICAL TRIALS 2022-2023

## Academic sponsor

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<td>SIOP HRMB</td>
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<td>IntReALL 2020</td>
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<td>PROTEICO</td>
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<td>SCRIPT-AML</td>
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<td>YCMB-LR</td>
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## Commercial sponsor

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<td>S. Ryhänen/HUS</td>
<td>2023</td>
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</tbody>
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Katja Eloranta / Minna Koskenvuo / Virve Pentikäinen 14.09.2022
THANK YOU

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