Clinical Research involving Children: Challenges and Opportunities

Developed by the Clinical Trial Unit (CTU) Basel in collaboration with University Children’s Hospital Basel (UKBB)
Dendritic Cells: Artistic coloration of a human dendritic cell, illustrating its characteristic star-like shape and central role in our immune system.

Dendritic cells are antigen-presenting cells of the mammalian immune system. Their main function is to process antigen material and present it on the cell surface to the T cells of the immune system. Once activated, dendritic cells can migrate to lymph nodes where they interact with T cells and B cells to initiate an adaptive immune response. At certain development stages they grow branched projections, the dendrites (or „veils“) that give the cell its name.

Dendritic cells are also able to develop sheet-like processes that fold back onto the membrane surface. When exposed to e.g. HIV, these sheets entrap viruses in the vicinity and focus them to contact zones with T-cells targeted for infection.

The dendritic cell were first described by Paul Langerhans (hence „Langerhans cell“) in the late nineteenth century. In 1973 Ralph M. Steinman and Zanvil A. Cohn established the term „dendritic cell“. For discovering the central role of dendritic cells in the adaptive immune response, Steinman was awarded the Nobel Prize in Physiology or Medicine in 2011.

This image was produced using scanning electron microscopy in combination with selectively assigning different colors to different structures. By creating a 3D-like photorealistic appearance, the artist aims to expose the complex structure and cellular interaction of an activated dendritic cell.
Welcome

The Clinical Trial Unit (CTU) Basel is part of the Departement of Clinical Research and serves as a multidisciplinary competence center for clinical research at the University Hospital Basel. It provides support mostly to academic research groups regarding all aspects of planning and conduct of a clinical research project. Additionally, the CTU Basel has developed a comprehensive portfolio of different training and educational programs for different target audiences like study physicians, study nurses, study coordinators and others.

The course «Clinical Research involving Children: Challenges and Opportunities» is a joint initiative by the University Children’s Hospital Basel and the CTU Basel and aims at providing a paediatric specific training program for researchers and research staff. Contents are based on the the Swissethics mandatory learning objectives for sponsor-investigators in clinical trials and strongly relate to every day practice in paediatric clinical research. This course is intended to inspire patient-oriented research in this challenging but highly significant field.

With kind regards and best wishes for a successful training event

Dr. Barbara C. Peters
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Challenges and opportunities

Conducting clinical trials with children and adolescents entails special challenges for clinical researchers. This patient group represents a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development-related research important for their benefit. This one-day training course conveys the most important aspects of research with and for children and adolescents. The following topics will be covered:

- Responsibilities of paediatric sponsor-investigators, incl. feasibility assessment, budget-planning and study procedures
- Clinical-pharmacological concept of drug-development with children and adolescents
- Study-types and study-design in paediatrics, including therapy-optimizing studies and randomized controlled trials (RCTs) in paediatrics
- Challenges for study staff in paediatric trials
- Experiences with a paediatric research platform

Target audience

In combination with a basic course on GCP (e.g. «GCP Basiskurs» by the CTU Basel), this advanced course results in a certificate at the level «sponsor-investigator» which is mandatory by Swissethics for principal investigators in clinical trials without external sponsor, so-called investigator-initiated trials (IITs).

Swissethics also recommends this course for all study physicians and study staff involved in clinical trials and research projects with children and adolescents. Finally, all physicians, scientists, students and medical staff in paediatrics will profit from the insights into patient-oriented research covered in this course.

Course direction

- Prof. Dr. med. Marc Pfister, Vice-Chair, Paediatric Pharmacology, University Children’s Hospital Basel (UKBB)
- Prof. Dr. med. Johannes van den Anker, Chair, Paediatric Pharmacology, University Children’s Hospital Basel (UKBB)

Time and venue

One-day course, November 18, 2015
Auditorium, University Children’s Hospital Basel (UKBB)
Registration and further information

For current course dates, course fees and registration form please visit our website: [www.clinicaltrialunit.ch/ausundweiterbildung](http://www.clinicaltrialunit.ch/ausundweiterbildung), click on → GCP-Kurse