

**Central European Pediatric Oncology
Early Trial Alliance**

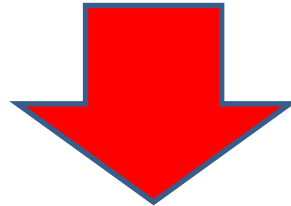
Regina Demlova

CEPOETA

- A non-profit organization supporting the clinical research in pediatric oncology in CEE region, particularly in the area of innovative clinical trials for children and young adults.

CEPOETA mission

- Create an international framework of experts on clinical trials in children

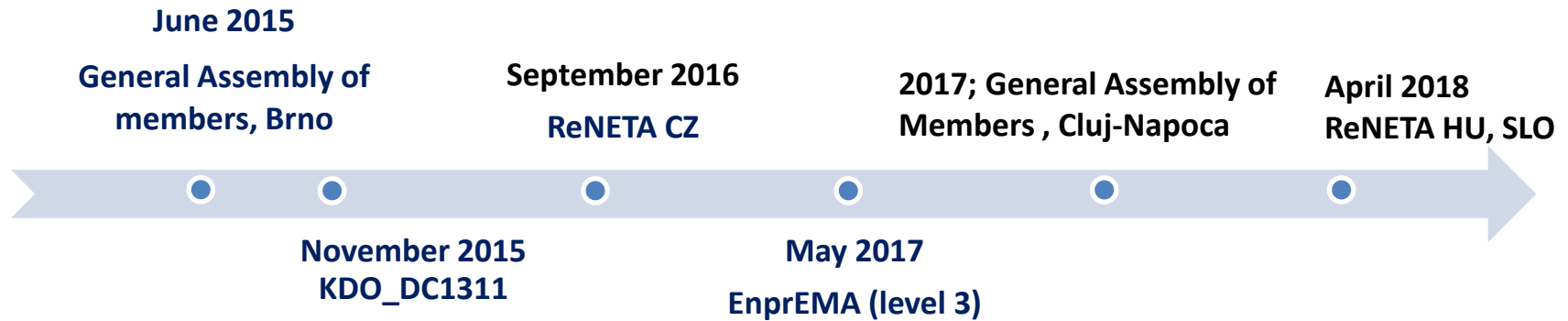


- Increase the number of multicenter clinical trials for children with cancer in Central and Eastern Europe.
- Access to new innovative drugs for children with cancer within the EU

CEPOETA mission

- Intermediate communication and cooperation
 - state authorities (regulators)
 - pediatric oncology healthcare facilities
 - parents and children in the area of pediatric oncology
 - Patient organizations

CEPOETA milestones



CEPOETA management

- General Assembly
- President (Prof. Valík D., former CHMP member)
- Council:
 - Ass. Prof. Valík
 - Ass. Prof. Demlová
 - Dr. Koščík
- Advisory board
- Secretary



CEPOETA Membership

Membership in CEPOETA is open to:

- *legal entities involved in research or provision of healthcare in the area of pediatric oncology*
- *persons that pursue conduct of clinical studies in the field of pediatric oncology and other persons that possess relevant knowledge and capacity to support the main activities of CEPOETA*

- *Currently: Czech Republic, Slovakia, Slovenia, Hungary, Romania, Macedonia, Bulgaria, Serbia*

Membership - Application for membership of association – available in print and on CEPOETA's website

CEPOETA meetings

- The members regularly meet on
 - The Regional Central-Eastern/South-Eastern European Pediatric Oncohematology Meeting,
 - The Romanian-Hungarian Pediatric Oncology Meeting
 - The Pediatric CELG Meeting

CEPOETA's website

- www.cepoeta.org



CEPOETA

The purpose of CEPOETA is support of research in pediatric oncology, particularly the area of early clinical trials for children and young adults.

CEPOETA in cooperation with ECRIN-ERIC



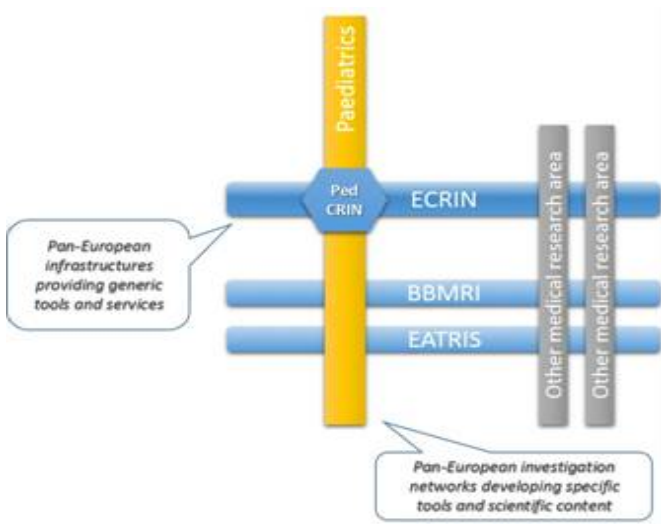
Central European Paediatric Oncology Early Trial Alliance



WP CZECRIN_{PED MED} - Pediatric Clinical Trials



- Partnership with pediatric investigation networks
- Development of tools for pediatric population
- Pilot trials on EU/national level



WP CZECRIN_{PED MED}

- CZECRIN_4Patients – pediatric research
- ReNETA
- KDO_DC113

CEPOETA clinical trials

Ongoing CT:

- Combined anticancer therapy with ex vivo manipulated Dendritic Cells producing interleukin-12 in pediatric, adolescent and young adults with progressive recurrent or primary metastatic malignancies of high risk
KDO_DC1311
EUDRA CT number: 2014-003388-39
- Recurrent Neuroblastoma and Ewing's sarcoma: Treosulphan based high dose chemotherapy with Autologous PBSC support
ReNETA study – submitted to national RA, EC
EUDRA CT number: 2015-002584-41

Planned CT (2018/2019)

- *16-33209A Genome-wide expression profiling and mutation analysis as the diagnostic basis for personalized pediatric cancer treatment plans: a feasibility study*
- *16-34083A Receptor tyrosin kinases and downstream signaling pathways as possible therapeutic targets in pediatric refractory solid tumors*

CEPOETA collaboration

- CEPOETA created a close collaboration with priority consumers, mainly patients and patients' groups in public health and health advocacy in CZ and across EU (<http://www.koaliceprozdravi.cz>; www.lpr.cz; <http://www.lymfomhelp.cz/>)
- New partnership with iCAN research – CEPOETA *initiated process of developing KIDS-Czech Republic for involving children and young people in clinical research in 2018*
- Planned partnership TEDDY Network - European Network of Excellence for Paediatric Clinical Research (*on process*)

CEPOETA as a EnpreEMA



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

An Agency of the European Union



Enpr-EMA

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Name	Country	Category	Coord. Group	Preterms < 1M	Infants 1M to < 24M	Children 2Y to < 12Y	Adolescents 12Y to < 18Y
Central European Pediatric Oncology Early Trials Alliance, z.s. Milady Horákové 1953/5a 602 00, Brno, Czech Republic/CEPOETA	Czech Republic	3	No	Yes	Yes	Yes	Yes

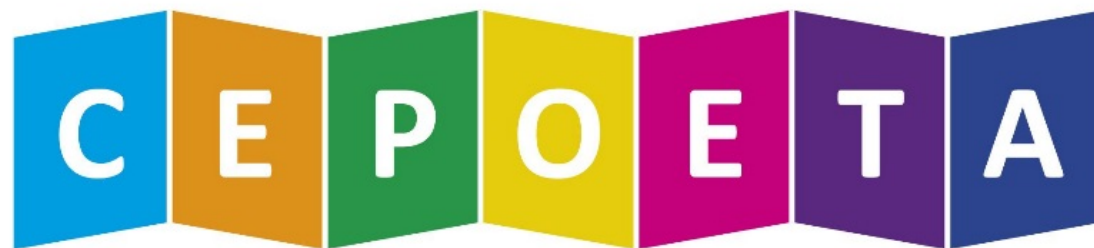
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CEPOETA activities

Increasing level of expertise of its members in the field of pediatric oncology and pediatric clinical trials in onkology

- Focus on keeping clinical research ethical standards
- Training course on Pediatric Pharmacovigilance
- Development QA/QC management system harmonised in CEE
- Clinical Data Management System (REDCap; OpenClinica) – implementation of GDPR rules
- Study coordinator/study nurses pediatric training programme – in cooperation with





THANK YOU