



H2020-TWINN-2015

Start date
01/01/2016

Duration
36 months

Project Coordinator
Dr. Marek MIGDAL
**INSTYTUT POMNIK CENTRUM
ZDROWIA DZIECKA (IPCZD)**



SMART

Winter School Agenda

Hotel Warszawianka, Jachranka

11-16.03.2018



Revision date
09/03/2018

Monday 12/03/2018 – Open session

9,30-10.00 Opening remarks and welcome (Marek Migdal, Piotr Socha)

10,00-11 Lectures

- 10 years of the Paediatric Regulation (Marek Migdal)
- How the new Regulations on clinical trials and data protection will change the paediatric drug research (Annagrazia Altavilla)
- The future of biomedical paediatric research in Europe (Adriana Ceci)

11,00 – 11,30 Coffee break

11,30 - Lectures

- Drug Design for paediatrics: problems and perspectives (Cosimo Altomare)
- Clinical trials in Poland (Marek Surowiec)
- Pharmacovigilance in paediatric clinical trials (Marek Surowiec)

Lunch 13.30 – 14.30

14,30-17,30 Lectures

- Dose Rationale, Data Generation and Evidence Synthesis in the Evaluation of Paediatric Medicines (Oscar Della Pasqua)
- Trial management (Donato Bonifazi, TC)
- Formulating better oral dosage forms for children (Nunzio Denora)

16,00 – 16,15 Coffee break

- The involvement of children/patients in planning paediatric research (Marek Migdal)
- The revised version of the EC Ethical Considerations on paediatric trials (Annagrazia Altavilla)
- Secondary use of data to enhance paediatric research (Fedele Bonifazi)

Final remarks

Tuesday 13/03/2018 – morning (9-11 – coffee break – 11.30-13)

- Publication procedures and rules according to SMART project (Marek Migdal)
- Introduction from the faculty on the topic (Clinical Trials) and the scope of training (CVBF, Annagrazia Altavilla)
- Trainees presentation on the training projects (20 min each + discussion with tutor)
 - Jacek Kołodziejczyk - CVBF „Experts in paediatric clinical trials, planning and performing”
 - Katarzyna Żyluk - CVBF „Pharmacovigilance”
 - Aleksander Wiśniewski - UCL: „Guidelines of collecting blood samples for clinical trials performed with venous and arterial blood, including the specifics of pediatric patients”
- Comments and suggestions, proposal for publication discussion (CVBF and UCL tutors)

Tuesday 13/03/2018 – afternoon (14-16 – coffee break – 16.30-18)

- Introduction from the faculty on the topic (PK/PD-Extrapolation) and the scope of training (Oscar Della Pasqua, Sean Oosterholt)
- Trainees presentation on the training projects (20 min each + discussion with tutor)
 - Agnieszka Czajkowska UCL: „Creation of pharmacological models for CMHI”
 - Jacek Rubik UCL: „Kidney transplantation: PKPD model and drug dosing”
 - Eliza Michalska UCL „PK-PD data M&S modelling on pain relievers simulation in neonates”
 - Mariya Tsupruk UCL „PK-PD data M&S modelling on pain relievers simulation in children”
- Comments and suggestions, proposal for publication discussion (UCL TUTORS)

Wednesday 14/03/2018 – morning (9-11 – coffee break – 11.30-13)

- Introduction from the faculty on the topic (Formulations) and the scope of training (Cosimo Altomare, Nunzio Denora)
- Trainees presentation on the training projects (20 min each + discussion with tutor)
 - Aleksandra Sobczyk UNIBA „Development of the new paediatric formulation – step 1”
 - Ryszard Sot UNIBA: „ Development of the new paediatric formulation – step 2”
 - Piotr Salwa UNIBA : „Development of the new paediatric formulation – step 3”
 - Katarzyna Witulska UNIBA: „Development of the new paediatric formulation – step 4”

- Comments and suggestions, proposal for publication discussion (using the example of spironolactone) (UNIBA tutors)

Wednesday 14/03/2018 – afternoon (14-16 – coffee break – 16.30-17.30)

3 Breakout sessions: the work of tutors with their trainees on the outcomes of the training projects:

- 1- Paediatric Clinical trials
- 2- PK/PD models, extrapolation
- 3- Paediatric Formulations

Thursday 15/03/2018 – morning (9-11 – coffee break – 11.30-13)

- The Polish Paediatric research network and the role of SMART trainees (Marek Migdal)
- 3 Breakout sessions (cont.): the work of tutors with their trainees on the outcomes of the training projects:
 - 1- Paediatric Clinical trials
 - 2- PK/PD models, extrapolation
 - 3- Paediatric Formulations

Thursday 15/03/2018 – afternoon (14-16)

- Survey on trainees' satisfaction
- Questionnaire on trainees' advancements

Coffee break

16.30-18

- Results from the survey
- Proposals for the open meeting and final remarks of the Faculty

Friday 16/03/2018 – morning (9-10.30)

- Tutors recap