



Ninth FORESIGHT TRAINING COURSE

In collaboration with

Master in "Regulatory Sciences - GIANNI BENZI" (*University of Pavia*)

Italian Society of Regulatory Affairs (*SIAR*)

European Network of Excellence for Paediatric Clinical Research
(*TEDDY-Network*)

EUROPE LEADS THE BEST MEDICINES SYSTEM FOR PATIENTS

EMA scientific, economic and social role,
Orphan and innovative therapies,
Paediatric medicines,
Evidence, risks and benefits from drug uses,
Patients' role and contribution

27-29 October, 2016

Pavia (Italy)

DRAFT AGENDA



Thursday, 27 October 2016

14,00 **Welcome Address**

Authorities

14,15 **Introduction**

The Gianni Benzi Foundation role and perspective

Gianni Benzi Foundation representative

Regulatory sciences in Pavia: from the school to the master

Pavia Master representative

The European Medicines System

14,30 **EMA: past, present and future of the European Medicines System**

EMA representative

15,00 **European MA of Medicines: results and future challenges**

EU Commission representative

15,30 **Benefits for Patients**

Patient Association representative

Coffee break

16,30 **The challenging role of the National Agencies facing innovation**

AIFA representative

17,00 **Public-Private collaboration in the EU Framework**

Industry representative

17,30 **Q&A**

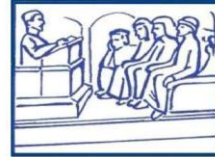
All speakers and discussants



Friday, 28 October 2016

Orphan and Innovative therapies

- 09,00 **Regulation of OMPs (incentive, timing, barriers and opportunities)**
COMP representative
- 09,45 **From designation to MA: successes and failures of OMPs**
EMA/ Gianni Benzi Foundation
- 10,30 **Q&A**
All speakers and discussants
- 11,00 **Coffee break**
- 11,30 **Regulation of ATMPs (incentive, timing, barriers and opportunities)**
CAT representative
- 12,15 **Gene therapies for rare diseases**
- 11,45 **Perspectives for Duchenne dystrophies**
Patients association representative
- 12,15 **Q&A**
All speakers and discussants
- 13,00 **Lunch**



Paediatric Medicines

- 14,30 **10 years of Paediatric Regulation: what's on the corner**
PDCO/Paediatric networks
- 15,00 **Paediatric Medicines and Young Patients Advocacy**
iCAN representative
- 15,30 **Paediatric study issues: sites identification, recruiting, paediatric expertise, research management, pharmacovigilance**
CVBF-TEDDY representative
- Coffee break**
- 16,30 **How is changing paediatric research: innovative tools and methods**
PDCO/GRiP
- 17,00 **Global Paediatric Network initiative**
EnprEMA representative
- 17,30 **Q&A**
All speakers and discussants



Saturday, 29 October 2016

Evidence, risks and benefits from drug uses

- 9,00 **The new clinical trials regulation to improve the clinical research in Europe**
AIFA representative
- 9,30 **Secondary use of patients data in the light of the new European Legislation**
EMA representative
- 10,00 **Registries and Big data use**
EMA/AIFA representative
- 10,30 **Scientific Advice and Protocol assistance: results and future developments**
Industry representative
- Coffee Break**
- 11,00 **European procedures for early approval and PRIME**
CHMP representative
- 11,30 **Real availability of the Medicines: steps after the MA**
Patients Association representative
- 12,00 **SIAR proposal for timely access of priority Medicines**
SIAR representative
- 13,00 **Q&A and final remarks**
All speakers

Lunch and goodbye