



FORESIGHT  
TRAINING  
COURSE **IX**

**GIANNI BENZI**  
PHARMACOLOGICAL  
RESEARCH FOUNDATION



Collegio Fratelli  
Cairoli



Comune di Pavia



UNIVERSITÀ  
DI PAVIA

## EUROPE LEADS THE BEST MEDICINES SYSTEM FOR PATIENTS

27-29 October, 2016 Collegio Fratelli Cairoli - Piazza Collegio Cairoli, 1, Pavia - Italy

### MAIN TOPICS:

EMA scientific, economic and social role

Orphan and innovative therapies

Paediatric medicines

Evidence, risks and benefits from drug uses

Patients' role and contribution



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)



The 'Gianni Benzi' Pharmacological Research Foundation Foresight Training Courses are devoted to elucidated the complex European regulatory system allowing medicinal and other products for human use be developed and marketed according to common rules and agreed criteria. Each course is focused on the most recent innovation and advancement in the field and aims to put together different stakeholders and experts in the sector willing to share their experiences and knowledge.

The IX Foresight Training Course is organised in collaboration with the Master in "Regulatory Sciences

- GIANNI BENZI" (University of Pavia) and is aimed at providing a special acknowledgment to Prof Gianni Benzi for his significant contribution to the European Medicines System setting up and implementation.

It is a 3-day meeting that will host key opinion leaders and experts coming from different European- and non-European Countries and, as the previous editions, will represent the right opportunity for academy, companies, regulatory experts and investigators to debate and discuss the main current issues on regulatory sciences, and for students to learn about best practices and interdisciplinary collaboration.

- 13,30 **Welcome Address - *Con il patrocinio del Ministero della Salute***  
Authorities
- 14,00 **Introduction**  
**The Gianni Benzi Foundation role and perspective**  
*Adriana Ceci*, Gianni Benzi Pharmacological Research Foundation - President  
**Regulatory sciences in Pavia: from the school to the master**  
*Maurizia Dossena*, Post-Degree Master in Regulatory Sciences 'G. Benzi' - Coordinator

## 1<sup>st</sup> SESSION ■ The European Medicines Regulatory System: Past, Present and Future

- Chair: *Adriana Ceci***
- 14,30 **The European Medicines System for science and society**  
*Joseph Torrent-Farnell*, Hospital de la Santa Creu I Sant Pau - Clinical Head of Clinical Pharmacology; EMA - COMP member and past Chair
- 15,00 **Towards a EMA framework of collaboration with academia**  
*Monica Ensini*, European Medicines Agency (EMA) - National Expert on Secondment at Public Engagement Department
- 15,30 **European Regulatory System after Brexit: Institutional and Legal issues**  
*Stefano Marino*, European Medicines Agency (EMA) - Head of Legal Service
- 16,00 **Coffee break**
- 16,30 **Round Table - The Main Stakeholders' points of view:**  
**Chair: *Fedele Bonifazi*** - Gianni Benzi Pharmacological Research Foundation - Vice-President  
*Marialuisa Lavitrano*, BBMRI-ERIC - Co-Chair of Management Committee; CNRB - President  
*Angela Del Vecchio*, Agenzia Italiana del Farmaco (AIFA) - Head of Good Clinical Practice and Pharmacovigilance Inspectorate Office  
*Nathalie Dompé*, Dompé Farmaceutici - CSR  
*Anna Cieslik*, Polish Office for Registration Director of Department of Assessment of Medicinal Products; EMA - Member of CAT  
*Domenico Valle*, Eli Lilly Italia - Regulatory Affairs Director; Farmindustria - Member of Regulatory Affairs group  
*Francois Houyez*, EURORDIS - Director of Treatment Information and Access and Health Policy Advisor
- 18,30 **Q&A** - All speakers and discussants

## ■ 2<sup>nd</sup> SESSION ■ Paediatric Medicines

- Chair: *Marek Migdal***
- 09,00 **Introduction**  
*Marek Migdal*, Deputy Head, PICU, Children's Memorial Health Institute, PDCO EMA member
- 09,10 **10 years of Paediatric Regulation: what's on the corner**  
*Paolo Rossi*, Italian Network for Paediatric Clinical Trials Coordinator
- 09,40 **How is changing paediatric research: innovative tools and methods**  
*Paola Baiardi*, Istituti Clinici Scientifici Maugeri - Coordinator of Scientific Unit; EMA - Member of PDCO
- 10,10 **GRIP Network: a bridge to the future**  
*Carlo Giaquinto*, Fondazione Penta - President; GRIP Network - Coordinator
- 10,40 **The features of paediatric clinical trials from feasibility analysis to results**  
*Donato Bonifazi*, Consorzio per Valutazioni Biologiche e Farmacologiche - Chief Executive Officer
- 11,10 **Coffee break**
- 11,40 **Paediatric Medicines and Young Patients Advocacy**  
*Joana Claverol Torres*, Hospital Sant Joan de Déu Barcelona - Coordinator of the Clinical Trials Unit
- 12,10 **Global Paediatric Network initiative**  
*Mark Turner*, Enpr-EMA - Co-Chair; Liverpool University - Senior Lecturer
- 12,40 **Q&A** - All speakers and discussants
- 13,00 **Lunch**

### 3<sup>rd</sup> SESSION ■ Orphan and Innovative therapies

Chair: **Enrico Bosone**

- 14,00 **Introduction**  
*Enrico Bosone*, SIAR - President
- 14,10 **Regulation of Orphan Medicinal Products (incentives, timing, barriers and opportunities)**  
*Joseph Torrent-Farnell*, Hospital de la Santa Creu I Sant Pau - Clinical Head of Clinical Pharmacology; EMA - COMP member and past Chair
- 14,30 **Regulation of Advanced Therapy Medicinal Products (incentive, timing, barriers and opportunities)**  
*Anna Cieslik*, Polish Office for Registration Director of Department of Assessment of Medicinal Products; EMA - Member of CAT
- 14,50 **Pricing and Reimbursement rules allowing early patients access to orphan medicines: the AIFA example**  
*Pierluigi Russo*, Agenzia Italiana del Farmaco (AIFA) - Head of pharmaceutical policy office
- 15,10 **Coffee break**
- 15,30 **Innovative cell\_based therapy of hand disability in patients with systemic sclerosis**  
*Florence Sabatier*, Aix-Marseille University - Professor of Hematology and Immunology; Assistance Publique Hopitaux de Marseille - Head of cell therapy department
- 15,50 **Innovative therapies for rare diseases**  
*Silvia Priori*, Istituti Clinici Scientifici Maugeri - Head of Scientific Unit; University of Pavia - Professor of cardiology
- 16,10 **Perspectives for Duchenne dystrophies**  
*Filippo Buccella*, EUPATI Italia - Chair of the Executive Committee, Patients Academy
- 16,30 **Regulatory hurdles and key considerations during development of Holoclar**  
*Giovanni Milazzo*, Chiesi Farmaceutici - Head of ATMP Regulatory Affairs
- 16,50 **Corrective gene therapy for ADA-SCID affected children**  
*William Zamboni*, GSK - Medical Director, Immunology and Rare Diseases
- 17,10 **Q&A** - All speakers and discussants

### 4<sup>th</sup> SESSION ■ Evidence, risks and benefits from drug uses

Chair: **Stefano Marini**

- 09,00 **Introduction**  
*Stefano Marini*, European Contract Research Organization Federation (EUCROF) President
- 09,10 **From designation to Marketing Authorisation: successes and failures of Orphan Medicinal Products**  
*Viviana Giannuzzi*, Gianni Benzi Pharmacological Research Foundation - Coordinator of R&D area
- 09,40 **Evidence, risks and benefits for patients from drug uses**  
*Francois Houyez*, EURORDIS - Director of Treatment Information and Access and Health Policy Advisor
- 10,10 **European Union market segmentation of botanical products between traditional medicinal products of plant origin and botanical food supplements**  
*Vittorio Silano*, Gianni Benzi Pharmacological Research Foundation - President of Scientific Committee
- 10,40 **Coffee Break**
- 11,00 **The new Framework to conduct trials facilitating early market approval**  
*Domenico Criscuolo*, GENOVAX - President
- 11,30 **The new European initiatives to support products development and innovation**  
*Vincenzo Salvatore*, Insubria University - Professor of International law
- 12,00 **SIAR proposal for timely access of priority Medicines**  
*Enrico Bosone*, SIAR - President
- 12,30 **Q&A and final remarks**
- 13,00 **Light lunch and goodbye**



Via Abate Eustasio, 30 - 70010 Valenzano (BA) Italy

Telephone / Fax: +39 080 202 11 69

VAT Number 06780820723 - Tax Code 93347800729

[info@benzifoundation.org](mailto:info@benzifoundation.org) - [www.benzifoundation.org](http://www.benzifoundation.org)