







## **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

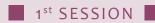
Thursday, 27 October 2016

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



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



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** 



Chair: Enrico Bosone

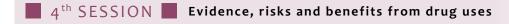
- 14,00 Introduction
  - Enrico Bosone, SIAR President
- 14,10 Regulation of Orphan Medicinal Products (incentives, timing, barriers and opportunities)

  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



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
- 69,40 Evidence, risks and benefits for patients from drug uses
   Francois Houyez, EURORDIS Director of Treatment Information and Access and Health Policy Advisor
- 10,10 EuropeanUnionmarketsegmentationofbotanicalproductsbetweentraditionalmedicinal 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



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