GIANNI BENZI
PHARMACOLOGICAL RESEARCH
FOUNDATION

Master Biennale di II livello in
Discipline Regolatorie "G. Benzi"
Università degli Studi di Pavia

Gianni Benzi Pharmacological Research Foundation
Ninth FORESIGHT TRAINING COURSE

EUROPE LEADS THE BEST MEDICINES SYSTEM FOR PATIENTS

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

27-29 October, 2016

Collegio Fratelli Cairoli

Piazza Collegio Cairoli, 1, Pavia - Italy

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)

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Course presentation

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.

AGENDA

Thursday, 27 October 2016

13,30 **Welcome Address**

Authorities

14,00 **Introduction**

The Gianni Benzi Foundation role and perspective

Adriana Ceci, Gianni Benzi Foundation - President

Regulatory sciences in Pavia: from the school to the master

Maurizia Dossena, Post-Degree Master in Regulatory Sciences 'G. Benzi' - Coordinator

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1° Session: The European Medicines Regulatory System: Past, Present and Future

Chairs: ***Adriana Ceci, Vittorio Silano***

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:**

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

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

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Friday, 28 October 2016 (morning session)

2° Session: Paediatric Medicines

Chair: ***Marek Migdal***

09,00 **Introductory Remarks**
Nathalie Dompé, Dompé Farmaceutici

09,10 **10 years of Paediatric Regulation: what's on the corner**
Paolo Rossi, Paediatric Hospital 'Bambino Gesù' and Tor Vergata University – Chair of Clinical Trial Centre

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**

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Friday, 28 October 2016 (afternoon session)

3° Session: Orphan and Innovative therapies

Chair: ***Enrico Bosone***

14,00 **Regulation of Orphan Medicinal Products (incentives, timing, barriers and opportunities)**
Joseph Torrent-Farnell, Hospital de la Santa Creu I Sant Pau – Head of Clinical Pharmacology; EMA – COMP member and past Chair

14,20 **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

14,40 **Pricing and Reimbursement rules allowing early patients access to orphan medicines: the AIFA example**
Pierluigi Russo, Italian Medicines Agency (AIFA) - Head of pharmaceutical policy office

15,00 **Q&A -** All speakers and discussants

15,20 **Coffee break**

15,40 **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

16,00 **Innovative therapies for rare diseases**
Silvia Priori, Istituti Clinici Scientifici Maugeri - Head of Scientific Unit; University of Pavia – Professor of cardiology

16,20 **Corrective gene therapy for ADA-SCID affected children**
William Zamboni, GSK - Medical Director, Immunology and Rare Diseases

16,40 **Regulatory hurdles and key considerations during development of Holoclar**
Giovanni Milazzo, Chiesi Farmaceutici – Head of ATMP Regulatory Affairs

17,00 **Perspectives for Duchenne dystrophies**
Filippo Buccella, EUPATI Italia - Chair of the Executive Committee, Patients Academy

17,20 **Q&A -** All speakers and discussant

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Saturday, 29 October 2016

4° Session: Evidence, risks and benefits from drug uses

Chairs: **Stefano Marini**

09,00 **Introductory Remarks**
Vittorio Silano, Fondazione Gianni Benzi Onlus – President of Scientific Committee

09,10 **European procedures for early approval and PRIME**
Agnes Gyurasics, Hungarian National Institute of Pharmacy - Chief Advisor to the General Director; EMA - Member of PDCO and CHMP

09,40 **From designation to Marketing Authorisation: successes and failures of Orphan Medicinal Products**
Viviana Giannuzzi, Gianni Benzi Foundation - Coordinator of R&D area

10,10 **Evidence, risks and benefits for patients from drug uses**
Francois Houyez, EURORDIS – Director of Treatment Information and Access and Health Policy Advisor

10,40 **The new Framework to conduct trials facilitating early market approval**
Domenico Criscuolo, GENOVAX – President

11,10 **Coffee Break**

11,40 ***The new European initiatives to support products development and innovation***
Vincenzo Salvatore, Insubria University – Professor of International law

12,10 **SIAR proposal for timely access of priority Medicines**
Enrico Bosone, SIAR - President

12,40 **Q&A and final remarks**

13,10 **Light lunch and goodbye**