THE EUROPEAN MEDICINES REGULATORY NETWORK: PRESENT AND FUTURE

X Foresight Training Course

organised by

Gianni Benzi Pharmacological Research Foundation

Master in Regulatory Sciences 'Gianni Benzi'- University of Pavia

In collaboration with

Istituti Clinici Scientifici Maugeri

Società Italiana Attività Regolatorie

27th – 28th October, 2017

Aula Adolfo Bogoncelli, Istituti Clinici Scientifici Maugeri - Pavia (Italy)

Course Scientific Committee

Viviana Giannuzzi - Gianni Benzi Foundation, *Maurizia Dossena* - University of Pavia, *Paola Baiardi* - Istituti Clinici Scientifici Maugeri, *Enrico Bosone* - Società Italiana Attività Regolatorie

Supported by

Italian Medicines Agency

National Institute of Health

University of Pavia

COURSE OBJECTIVES:

- To describe the main interesting innovations in the European Pharmaceutical System

- To putting the patients in the core of the system

-To address the appropriate use of experimental and real world data as sources of clinical evidence

-To revise criteria for sustainability and appropriateness of pharmaceutical care

27 October 2017

Welcome address Gianni Benzi Foundation – Adriana Ceci Master in Regulatory Sciences 'Gianni Benzi' – Maurizia Dossena University of Pavia – Francesco Svelto Società Italiana Scienze Regolatorie – Enrico Bosone Istituti Clinici Scientifici Maugeri	9.00

Lectures The European regulatory system: plans and actions at a glance Gianni Benzi Foundation Data Protection and Privacy: the new European Regulation A. Spina EMA – European Medicines Agency	9.30
Discussion	

First Session ***Experimental and Real world data: collect, archive and share to increase their value in research*** ***Chair: A. Ceci***		
Quantitative methods and evidence synthesis using healthcare data	O. Della Pasqua University College London	10.30
How to use data from registries to enhance the evidence for patients cure	F. Bonifazi Gianni Benzi Foundation	11.00
Gain evidence from innovative study designs for clinical trials	P. Baiardi Istituti Clinici Scientifici Maugeri	11.30
Harnessing the Power of Real World Data	G. Pasciullo Bluebirdbio	12.00
How to share health data	L. Sacchi University of Pavia	12.30
Discussion		13.00

Discussants
A. Spina EMA – European Medicines Agency A. Altavilla Aix-Marseille University

Second Session ***HTA programs at European and National level*** ***Chair: P.Lago***		
The Health technology assessment (HTA): a national framework to advance welfare systems	M. Marchetti ISS – Istituto Superiore di Sanità	14.30
Scientific network with HTA bodies, Payers and Patients		15.00
Outcomes research and outcomes management in the light of health assessment	I. Springhetti Istituti Clinici Scientifici Maugeri	15.30
Health technology assessment (HTA) criteria in the light of current R&D trends	G. Giuliani Roche	16.00
Discussion		16.30

Discussants
F. Panzeri Quintiles F. Bonifazi Gianni Benzi Foundation

17.30 end of the day

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Third Session *Innovative Medicines access in the EU* *Chair: A. Spina*		
How to cover OMP availability in EU: EMA role and efforts	J. Torrent Farnell Hospital de la Santa Creu I Sant Pau; EMA - COMP	9.00
Experiences in the advocacy for Patients' Rights	M. Votta Active Citizenship Network	9.30
OMP registries: are they a tool to cover the gap?	V. Giannuzzi Gianni Benzi Foundation	10.00
Timely access to therapies for severe diseases with unmet medical need	E. Bosone SIAR - Società Italiana Attività Regolatorie	10.30
Discussion		11.00

Discussant
D. Criscuolo Genovax

Lecture	
National Agencies: the role and relevance in the EU Regulatory Network M. Melazzini AIFA – Agenzia Italiana del Farmaco	11.30

Fourth Session ***Patients involvement and rights in the regulatory framework*** ***Chair: T. Iorno***		
Medicine Agencies responsibility of keeping patients informed while covering their needs		12.00
Individual data from clinical trials: how to protected the patient rights	J. Demotes European Clinical Research Infrastructure Network	12.30
Contribution of Expert Patients in the assessment' process of innovative medicines	L. A. Brunetta Fondazione Italiana "Leonardo Giambrone" per la Guarigione dalla Talassemia	13.00
Patients versus industry rights: where is the conflict of interest?		13.30
Involve the younger in safe medicinal development plans	L. Ruggieri Gianni Benzi Foundation	14.30
Protect the experimental patients population: a key role for Ethics Committees		15.00
Discussion		15.30

Discussant
D. Bonifazi Consorzio per Valutazioni Biologiche e Farmacologiche