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

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Regione Lombardia

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 Istituti Clinici Scientifici Maugeri – Paolo Migliavacca University of Pavia – Francesco Svelto Master in Regulatory Sciences 'Gianni Benzi' – Maurizia Dossena Farmindustria – Giovanni Giuliani	9.00
Introduction *A. Ceci – E. Bosone* The European regulatory system: plans and actions at a glance Gianni Benzi Foundation	9.30
Lecture Data Protection and Privacy: the new European Regulation A. Spina, EMA – European Medicines Agency	10.00

First Session ***Experimental and Real world data: collect, archive and share to increase their value in research*** *Chair: A. Ceci*		
Sharing and re-use of individual participant data from clinical trials	J. Demotes European Clinical Research Infrastructure Network	10.30
Share patients data for secondary use: the existing models and trends	F. Bonifazi Gianni Benzi Foundation	11.00
Quantitative methods and evidence synthesis using healthcare data	O. Della Pasqua University College London GlaxoSmithKline R&D	11.30
Gain evidence from innovative study designs for clinical trials	P. Baiardi Istituti Clinici Scientifici Maugeri	12.00
How to exploit the power of data variety for research and clinical practice	L. Sacchi University of Pavia	12.30
Discussants A. Spina, EMA – European Medicines Agency G. Giuliani, Farmindustria - Roche		13.00

Second Session ***HTA programs at European and National level*** *Chairs: P. Lago – J. Torrent Farnell*		
The Health technology assessment (HTA): a national framework to advance welfare systems	M. Marchetti ISS – Istituto Superiore di Sanità	14.30
Health technology assessment (HTA) criteria in the light of current R&D trends	G. Giuliani Farmindustria - Roche	15.00
Outcomes research and outcomes management in the light of health assessment	I. Springhetti Istituti Clinici Scientifici Maugeri	15.30
Harnessing the Power of Real World Data	G. Pasciullo Bluebirdbio	16.00
Discussants F. Panzeri, Quintiles F. Bonifazi, Gianni Benzi Foundation		16.30

17.00 end of the day

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Third Session ***Innovative Medicines access in the EU*** *Chairs: A. Spina – M. Migdal*		
Reconciling clinical evidence for Orphan Medicines and Access Policies	J. Torrent Farnell Catalan Health Service	9.00
Experiences in the advocacy for Patient' Rights	D. Quaggia Active Citizenship Network	9.20
OMP registries: are they a tool to cover the gap?	V. Giannuzzi Gianni Benzi Foundation	9.40
Timely access to therapies for severe diseases with unmet medical need	E. Bosone SIAR - Società Italiana Attività Regolatorie	10.00
Discussants D. Criscuolo, Genovax R. Barbon Galluppi, Federazione Italiana Malattie Rare Onlus		10.20

Lecture National Agencies: the role and relevance in the EU Regulatory Network M. Melazzini, AIFA – Agenzia Italiana del Farmaco	11.00

Fourth Session ***Patients involvement and rights in the regulatory framework*** *Chairs: T. Iorno – E. Bosone*		
Medicine Agencies responsibility of keeping patients informed while covering their needs	A. Cieslik Polish Office for Registration Director of Department of Assessment of Medicinal Products	12.00
Contribution of Expert Patients in the assessment' process of innovative medicines	L. A. Brunetta Fondazione Italiana "Leonardo Giambrone" per la Guarigione dalla Talassemia Thalassemia International Federation	12.20
Involve the younger in safe medicinal development plans	L. Ruggieri Gianni Benzi Foundation M. Lupo Consorzio per Valutazioni Biologiche e Farmacologiche	12.40
Protect the experimental patients population: a key role for Ethics Committees	M. Migdal Children's Memorial Health Institute	13.00
Discussants D. Bonifazi, Consorzio per Valutazioni Biologiche e Farmacologiche A. Altavilla, Aix-Marseille University		13.30