

Meeting
**Emerging complexity in medicine: how to translate
new scientific advancements into better patient care**

April 12-13, 2010

Organized by
ISTITUTO SUPERIORE DI SANITÀ
AGENZIA ITALIANA DEL FARMACO

This meeting was conceived based on the consideration that traditional procedures for developing new drugs should be revised and that the adoption of more integrated and flexible approaches could improve the quality and the effectiveness of these procedures and, as a consequence, patient care.

The “new rules” regarding these procedures will have to be well-defined and precise, based on sound scientific principles and shared by the scientific community, regulatory bodies and the industry. In light of the need to reach widespread agreement on potential new approaches, the meeting will also be attended by patient associations, whose views are not always taken into consideration yet which are expected to constitute an important contribution.

The Round Table discussion at the closing of the meeting will include decision makers at various institutional, industrial and political levels. The goal is for all stakeholders to engage in a synergic process aimed at overcoming stagnation by giving rise to innovation, taking into account new scientific advancements and paying greater attention to patient care.

April 12

14.00 Welcome and introductory remarks
F. Fazio, E. Garaci, G. Rasi

SESSION I
NEW APPROACHES TO CLINICAL TRIALS
Chairs: **E. Abadie, G. Nisticò**

14.45 *The future of drug development: advancing clinical trial design*
J. Orloff

15.05 *The Clinical Trials Transformation Initiative (CTTI)*
A. Grignolo

15.25 *New perspective and new challenges in clinical trial regulation in Italy*
C. Tomino

15.45 Coffee break

SESSION II
EVIDENCE-BASED MEDICINE: WHAT IT CAN AND CANNOT DO
Chairs: **L. Annunziato, J.L. Romàn-Pumar**

16.15 *Current understanding and evolution opportunities for Evidence-Based Medicine*
A. Miles

16.35 *Integrating the results of clinical research into clinical decision making*
M. R. Tonelli

16.55 *Evidence-Based Medicine and translational research*
D. Kumar

17.15 General Discussion

April 13

SESSION III
IN THE QUEST FOR NEW APPROACHES FOR HUMAN DISEASES
Chairs: **B. Ensoli, A. Giuliani**

9.30 *The discovery and development of HIV therapy*
S. Vella

Discussant
C.F. Perno

9.55 *Translating basic research in cancer patient care*
S. Pecorelli

Discussant
R. De Maria

10.20 *Drugs and clinical trials for neurodegenerative diseases*
P. Stanzione

Discussant
M. Pocchiari

10.45 *Rare diseases*
G. Remuzzi

Discussant
D. Taruscio

11.10 *Translation of advanced therapies*
F. Belardelli

Discussant
P. Popoli

11.35 Coffee break

SESSION IV
THE PATIENT POINT OF VIEW
Chair: **L.G. Spagnoli**

11.50 **A. Celano, R. Iardino, F. Merzagora**

12.35 Lunch

SESSION V
ROUND TABLE: HOW TO COPE WITH COMPLEXITY AND ADAPT NEW SCENARIOS TO PATIENT CARE
Chairs: **C. Cavazza, E. Garaci**

13.30 **C. Cursi, S. Dompé, G. Fioroni, R. Lauro, G. Rasi, A. Zangrillo**

CHAIRPERSONS AND SPEAKERS

Eric ABADIE - Agence Française de Sécurité Sanitaire des Produits de Santé, Saint-Denis Cedex, Paris - France

Lucio ANNUNZIATO - Chairman, Department of Neurosciences School of Medicine, University of Naples “Federico II”, Naples - Italy

Filippo BELARDELLI - Director, Department of Cell Biology and Neurosciences, Istituto Superiore di Sanità, Rome - Italy

Claudio CAVAZZA - President, Sigma-Tau, Pomezia (Rome) - Italy

Antonella CELANO - President, Associazione Pugliese Malati Reumatici, Lecce - Italy

Cesare CURSI - Senato della Repubblica, Rome - Italy

Ruggero DE MARIA - Director, Department of Haematology, Oncology and Molecular Medicine, Istituto Superiore di Sanità, Rome - Italy

Sergio DOMPÉ - President, Farmindustria, Rome - Italy

Barbara ENSOLI - Director, National AIDS Center, Istituto Superiore di Sanità, Rome - Italy

Ferruccio FAZIO - Minister, Italian Ministry of Health, Rome - Italy

Giuseppe FIORONI - Camera dei Deputati, Rome - Italy

Enrico GARACI - President, Istituto Superiore di Sanità, Rome - Italy

Alessandro GIULIANI - Department of Environment and Primary Prevention, Istituto Superiore di Sanità, Rome - Italy

Alberto GRIGNOLO - Corporate Vice President, Global Strategy and Services, PAREXEL Consulting, Waltham, MA - USA

Rosaria IARDINO - President, Network Persone Sieropositive, Milan - Italy

Dhavendra KUMAR - Consultant in Clinical Genetics, Institute of Medical Genetics, University Hospital of Wales, Cardiff University - UK

Renato LAURO - Rector, University of Rome "Tor Vergata", Rome - Italy

Francesca MERZAGORA - President, Osservatorio Nazionale sulla salute della Donna, Milan - Italy

Andrew MILES - Associate Dean of Medicine, University of Buckingham, London - UK

Giuseppe NISTICÒ - Director, Pharmaceutical Biotechnology Center, University of Rome "Tor Vergata", Rome - Italy

John ORLOFF - Senior Vice President, Novartis Pharmaceuticals, US Medical, East Hanover, NJ - USA

Sergio PECORELLI - President, Agenzia Italiana del Farmaco, Rome - Italy

Carlo Federico PERNO - Department of Experimental Medicine and Biochemical Sciences, School of Medicine, University of Rome "Tor Vergata", Rome - Italy

Maurizio POCCHIARI - Department of Cell Biology and Neurosciences, Istituto Superiore di Sanità, Rome - Italy

Patrizia POPOLI - Department of Therapeutic Research and Medicines Evaluation, Istituto Superiore di Sanità, Rome - Italy

Guido RASI - General Director, Agenzia Italiana del Farmaco, Rome - Italy

Giuseppe REMUZZI - Research Coordinator, Negri Bergamo Laboratories, Bergamo - Italy

José Luis ROMAN-PUMAR - Vice President MSD Europe, Managing Director Italy, Merck Sharp & Dohme, Rome - Italy

Luigi Giusto SPAGNOLI - Department of Diagnostic Imaging and Biopathology, University of Rome "Tor Vergata", Rome - Italy

Paolo STANZIONE - Stroke Unit, Department of Neuroscience University of Rome "Tor Vergata", Rome - Italy

Domenica TARUSCIO - Director, National Center for Rare Diseases, Istituto Superiore di Sanità, Rome - Italy

Carlo TOMINO - Head, Research and Clinical Trial, Agenzia Italiana del Farmaco, Rome - Italy

Mark R. TONELLI - Division of Pulmonary and Critical Care Medicine, University of Washington, Seattle, WA - USA

Stefano VELLA - Director, Department of Therapeutic Research and Medicines Evaluation, Istituto Superiore di Sanità, Rome - Italy

Alberto ZANGRILLO - Director, Specialization School of Anesthetist and Intensive Therapy, Vita-Salute San Raffaele University Milan - Italy

Technical and Scientific Secretariat

Dr. P. POPOLI, Dr. S. VELLA

Department of Therapeutic Research and Medicines Evaluation

Istituto Superiore di Sanità

Viale Regina Elena, 299 - 00161 Rome, Italy

Ph. +39 0649902482-6015

Fax +39 0649387104

E-mail: patrizia.popoli@iss.it; stefano.vella@iss.it

Organizing Secretariat

G. CARICATI, F. GIULIANO, V. LORENZINI

Office of the President

Istituto Superiore di Sanità

Viale Regina Elena, 299 - 00161 Rome, Italy

Ph. +39 0644869455

Fax +39 0644869440

E-mail: presidenza@iss.it

GENERAL INFORMATION

Venue

Aula Pocchiari, Istituto Superiore di Sanità

Viale Regina Elena, 299 - Roma



Meeting EMERGING COMPLEXITY IN MEDICINE: HOW TO TRANSLATE NEW SCIENTIFIC ADVANCEMENTS INTO BETTER PATIENT CARE

April 12-13, 2010

Aula Pocchiari
Istituto Superiore di Sanità
Viale Regina Elena, 299 - Roma