EATRIS Conference
From Basic Research To Medical Innovation

7 – 8 October 2010
Rome, Italy
Dear Participants,

We are very excited that the European Commission has launched a program to support infrastructures for the biomedical sciences. After three years of frequent exchange and intense work, we are happy to present the EATRIS Infrastructure concept for the first time.

Our goal is to establish a pan-European infrastructure for biomedical translational research, providing researchers open access to state-of-the-art facilities, training and supporting services across Europe.

We are committed to make EATRIS a driving force for translational research in Europe which will improve public health by accelerating the development of innovative diagnostics and therapies for the benefit of patients.

On behalf of EATRIS I wish all of you an interesting conference and a stimulating exchange here in Rome.

Rudi Balling, EATRIS Project Coordinator
7 October 2010
Rome — Sala Pietro da Cortona, Musei Capitolini

18:00 – 18:30 Opening Ceremony

**Ferruccio Fazio**, Italian Health Minister

**Gianni Alemanno**, Mayor of Rome

**Enrico Garaci**, President of Italian National Institute of Health (ISS)

**Rudi Balling**, EATRIS Project Coordinator

18:30 – 20:00 Opening Lectures

Chairpersons: Rudi Balling, Filippo Belardelli

**The new European Innovation Strategy: Chances for Translational Research**

**Ruxandra Draghia-Akli**
Director Directorate Health, DG Research, European Commission

**Individualised Therapy: From Dream to Reality**

**Lance A. Liotta**
George Mason-Inova Health System Translational Research Centers, USA

20:00 Conference Dinner at Terrazza Caffarelli
8 October 2010
Rome – Ministry of Health

Session I
Chairpersons: Bo Angelin, Rudi Balling

9:00 – 9:30 Funding Biomedical Research – An International Institution Perspective
Laura Piovesan
European Investment Bank

9:30 – 10:00 Infrastructures as a Motor for Research
Carlo Rizzuto
Chair European Strategy Forum on Research Infrastructures, ESFRI (2008-2010)

10:00 – 11:00 Meeting Challenges in Translational Research – EATRIS: A Pan-European Action Plan
Rudi Balling
EATRIS Project Coordinator, Director Luxembourg Centre for Systems Biomedicine

- How EATRIS will Innovate Research, Speed Development and Capture Value
  Bernd Eisele
  CEO of Vakzine Projekt Management GmbH

- How We Make EATRIS Successful
  Frank de Man
  EATRIS Organisation, Business Development and Finance

11:00 - 11:30 Coffee Break

Session II
Chairpersons: Peter Luijten, Filippo Belardelli

11:30 – 12:00 Translational Research – Needs and Benefits from the Industrial Perspective
Sverker Ljunghall
Vice President Science Relations, Astra Zeneca

12:00 – 12:30 Importance of Innovative Translational Research for Patients
Françoise Rouault
French Muscular Dystrophy Association (AFM)

12:30 – 13:00 Finding New Ways for Regulatory Solutions
Christian Schneider
Chair EMA Committee for Advanced Therapies

13:00 – 13:30 Present and Outlook in Translational Research
Francesco Marincola
Chief Immunogenetics, NIH Clinical Center, Bethesda, USA

Light Lunch
Prof. Rudi Balling has studied human and animal nutrition at the University of Bonn, Germany and Washington State University, Pullman, USA. He received his PhD in reproductive biology from the University of Aachen.

Between 1985 and 1987 he was a postdoctoral fellow in the Mount Sinai Research Hospital in Toronto, Canada and from 1987 to 1993 he carried out research as a staff scientist at the Max Planck Institutes in Göttingen and Freiburg. In 1993 he became director of the Institute of Mammalian Genetics at the Helmholtz Center of Environment and Health in Munich. In 2001 he took over the position as Scientific Director of the Helmholtz Center of Infection Research in Braunschweig.

After a sabbatical at the Broad Institute / MIT, Boston, Rudi Balling joined the University of Luxembourg, in September 2009 to become the founding Director of the Luxembourg Centre for Systems Biomedicine (LCSB).
**Professional experience**

Dr. Ruxandra Draghia-Akli is Director of the Health Directorate at the Research DG of the European Commission.

Previously, Ruxandra Draghia-Akli served as Vice President of Research at Inovio Pharmaceuticals and VGX Animal Health.

Dr. Draghia’s research activities have focused on plasmid design, gene expression and tissue-specific promoters/enhancers and sequences for the efficient expression of either secreted or intracellular proteins for gene therapy and vaccination. She is recognised as a global leader in the field of nucleic acid delivery for therapeutic and vaccination applications. She is an inventor on more than a hundred patents and patent applications.

Throughout her career, Dr. Draghia has published numerous scientific papers and reviews in the areas of electroporation, plasmid components, growth and development, immune stimulation, vaccination, health, and well-being. She served as ad-hoc reviewer for granting agencies, annual meetings for gene therapy and endocrinology societies, and scientific journals in Europe and the USA.

**Education**

Dr. Draghia received an M.D. from Carol Davilla Medical School and a Ph.D. in human genetics from the Romanian Academy of Medical Sciences. Dr. Draghia also completed a doctoral fellowship at the University of Rene Descartes in Paris and a post-doctoral training at Baylor College of Medicine (BCM), Houston, Texas, USA, and served as faculty at BCM.

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**Speakers**

**Ruxandra Draghia-Akli**  
Director of the Health Directorate at the Research DG of the European Commission  
Ruxandra.Draghia-Akli@ec.europa.eu

**Bernd Eisele**  
CEO of Vakzine Projekt Management GmbH  
eisele@vakzine-manager.de

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Dr. Eisele graduated from Heidelberg Medical School in 1986.

Dr. Eisele began his career in industry as Clinical Project Manager at Behringwerke AG in 1988. In various positions he was responsible for the clinical development of recombinant and transgenic products in clinical phases I – III.

In 1996 Dr. Eisele joined Solvay Pharmaceuticals GmbH in Hannover, Germany, and was responsible for the international phase III development program of the company’s lead cardiovascular product.

In 1997 he became Medical Director and Head of Medical Marketing for Canada, Asia, the Middle East, Australia, New Zealand, and South Africa.

In 2002 he was appointed Global Product Director for psychiatry and became responsible for the world-wide marketing of Solvay Pharmaceuticals’ psychiatry products.

From February 2003 to March 2008 Dr. Eisele was Head of Research & Development at VPM, a Vaccine development organization, founded by the German Federal Ministry of Research and Education (BMBF) and funded by Federal grants. Since April 1, 2008 he is head of VPM.

At the same time Dr. Eisele was appointed as head of the Clinical Research Center of Hannover Medical School. In this position he is currently organizing and supervising >35 Investigator Initiated clinical trials (IITs) and is legally representing Hannover Medical School as sponsor.

Due to his experience in the field of vaccines, Dr. Eisele, besides other national and international board activities, also collaborated in WHO vaccine consensus conferences, e.g. the WHO consensus conference on Standardization and Evaluation of BCG vaccines.
Sverker Ljunghall
Professor emeritus of Medicine, Uppsala University and former Vice President AstraZeneca R&D
sverker@ljunghall.nu

Clinical experience
- Licensed physician, 1970
- Specialist in Internal Medicine and Endocrinology 1977
- Head of Department of Medicine at the University Hospital, Uppsala 1990-1997

Industry experience
- Joined the pharmaceutical industry (Astra) 1998, Head of Experimental Medicine until merger with Zeneca 1999
- Vice President, Head of Global Clinical Science in AstraZeneca 1999-2001
- Vice President and Head of Global Clinical Development, 2001-2006 responsible worldwide, for all clinical trials in all therapeutic areas
- Vice President Science Relations 2006 – June 2010, reporting to head of R&D
- Member of EFPIA Research Directors Group 2006-2010

Scientific experience
- PhD 1977 in Medicine
- Focussed on calcium metabolism, research has been conducted in a number of areas – nephrology, cardiovascular, endocrinology and bone – with approaches from basic science (intracellular signalling) through translation research to clinical studies and epidemiology
- Close to 400 publications in peer reviewed journals (PubMed), not including chapters, books and articles in Swedish
- Supervisor of some 25 PhD students,
- Professor of Medicine at Uppsala University 1990-2007
- Head of University Department of Medicine 1990-1997 (including subspecialties as cardiovascular, nephrology, haematology, transplantation, endocrinology, GI and Faculty of Medicine Board

Speakers

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Professor emeritus of Medicine, Uppsala University and former Vice President AstraZeneca R&D
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Speakers

Lance A. Liotta
Co-Director of the Center for Applied Proteomics and Molecular Medicine at George Mason University
Medical Director in George Mason-Inova Health System Translational Research Center
lliotta@gmu.edu

Professional experience
Dr. Lance A. Liotta is a professor of life sciences at George Mason University (GMU) and co-director of the university’s Center for Applied Proteomics and Molecular Medicine. He also serves as medical director of the Clinical Proteomics Laboratory in the George Mason University/Inova Health System Translational Research Centers.

Together with Dr. Petricoin, Dr. Lance Liotta has formed the Center for Applied Proteomics and Molecular Medicine at the GMU. The Center has formed a unique partnership between GMU and Inova Health System. George Mason-Inova Health System Translational Research Centers is a joint initiative to coordinate multiple programs to implement proteomics, nanotechnology, and genomics research in cancer, metabolic syndrome, cardiopulmonary diseases, and neurodegenerative and liver diseases. The Center has developed technology for the application of proteomics to cancer biology, early diagnosis, and individualized therapy, under a unique joint program with the Italian Istituto Superiore di Sanita. Discoveries made under this program are being tested in ongoing clinical trials.

Before joining the George Mason faculty in May 2005, Dr. Liotta was chief of the Laboratory of Pathology at the National Cancer Institute’s (NCI) Center for Cancer Research, and deputy director for Intramural Research at the National Institutes of Health.

Education
Dr. Liotta earned his medical degree from Case Western Reserve Medical and is licensed to practice medicine in the state of Maryland. He also holds a doctoral degree in biomedical engineering from Case Western Reserve University.

Patents and publications
Dr. Liottas research contributions have generated more than 90 issued patents and more than 650 peer-reviewed publications.

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Education
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Patents and publications
Dr. Liottas research contributions have generated more than 90 issued patents and more than 650 peer-reviewed publications.
Education

Dr. Marincola received his MD, summa cum laude from the University of Milan, and his surgery training at Stanford University where he also completed a postdoctoral fellowship in surgical research.

Professional experience

Dr. Marincola is Chief of the Infectious Disease and Immunogenetics Section, Department of Transfusion Medicine, Clinical Center, National Institutes of Health, Bethesda, MD, USA. He joined the Surgical Oncology Branch of the National Cancer Institute, NIH, in 1990. Dr. Marincola was recently elected president of the International Society for the Biological Therapy of Cancer.

Editorial activities and publications

Dr. Marincola serves as the Editor-in-Chief, Journal of Translational Medicine and ASHI Quarterly; US Senior Editor of Immunotherapy, Associate Editor for The Journal of Immunotherapy, The Journal of Immunology, Tumori, and Clinical Cancer Research; Section Editor for Expert Opinion in Biological Therapy; Editorial Board, Cancer Immunology & Immunotherapy, The Journal of Experimental and Clinical Cancer Research.

Dr. Marincola is an author of about 450 peer reviewed research articles cited more than 13,000 times; his H Index is 58. He has been invited to speak at over 200 national and international meetings. Dr. Marincola is the second most cited scientist in melanoma during the last ten years, with 55 papers cited 3,704 times to date. Dr. Marincola’s record includes 63 papers cited a total of 2,955 times to date in the field of Clinical Medicine and 51 papers cited a total of 2,204 times to date in the field of Immunology.
Laura Piovesan
Managerial Adviser in Process and Life Science Industries, European Investment Bank
provesan@eib.org

Professional experience
European Investment Bank, Luxembourg
- March 2010 – Present
  Managerial Adviser in Process and Life Science Industries.
- 2000-2010
  Technical Adviser, Project Department, responsible for the technical and economic appraisal of projects submitted to the EIB for financing both in R&D infrastructure as well as in the Process and Life Sciences Industry.

Snamprogetti, Italy
- 1998-2000
  Strategic Planning Department - Industrial Economist, responsible for technical and economic feasibility, pre-feasibility and opportunity studies of industrial projects.
  Research & Development Department – Research Scientist, responsible for research projects in the field of catalysis, with competencies in Reaction and Reactor Engineering, Separation Technologies and Process Design.

Education
- 1991 Università di Padova, Italy, Degree in Chemical Engineering.

Christian K. Schneider
Head of Division EU Co-operation/Microbiology, Paul-Ehrlich-Institut, Federal Agency for Vaccines and Biomedicines, Langen, Germany
schci@pei.de

Membership in Scientific Committees of the European Medicines Agency (EMA)
- Chairman of the Committee for Advanced Therapies (CAT) (since 2009)
- Co-opted Member of the Committee for Medicinal Products for Human Use (CHMP) (since 2007)

Professional background
Since 2009 Head, Division EU Co-operation/Microbiology, Paul-Ehrlich-Institut
2007-2009 Acting Head, Division EU Co-operation/Microbiology, Paul-Ehrlich-Institut
2005-2007 Acting Head, Section Mono-/Polyclonal Antibodies, Paul-Ehrlich-Institut
2005-2003 Clinical Assessor, Section Mono-/Polyclonal Antibodies, Paul-Ehrlich-Institut

Education
- 2001-2003 Postdoctoral Fellow, Department Neuroimmunology, Max-Planck-Institute of Neurobiology, Martinsried, Germany
- 2000-2001 Research Fellow, Institute of Clinical Immunology, Department of Internal Medicine III, Nikolaus-Fiebiger-Institute of Molecular Medicine, Erlangen, Germany
- 1999-2000 Internship in Clinical Immunology, Rheumatology and Oncology, Department of Internal Medicine III, Friedrich-Alexander University Erlangen-Nuremberg, Germany
- 2000 MD degree in Medical Biochemistry, Friedrich-Alexander University Erlangen-Nuremberg

Areas of expertise and research interests
- Quality and Safety (Biological), including Advanced Therapies – Gene, Cell, and Tissue Therapies
- Biosimilars
- Unwanted immunogenicity of therapeutic proteins
- Clinical and experimental immunology including autoimmunity and neuroimmunology
- Clinical trials, including risk mitigation strategies for first-in-human clinical trials
Dr. Francoise Rouault joined the Scientific Direction of the French Muscular Dystrophy Association (AFM) in October 2009 as International Scientific Affairs Manager. After graduating in Molecular Genetics at the Université Libre de Bruxelles, Belgium, she joined as postdoctoral fellow the Research Institute of Molecular Pathology in Vienna, Austria. Subsequently she kept running fundamental research and teaching activities (Regulation of Gene Expression) and applied research activities for Gene Therapy (non viral and retroviral Vector Development). She worked at Transgene, Strasbourg from 1993 to 1997 where she constructed the first non viral vector for Duchenne Muscular Dystrophy selected by AFM for clinical development, at Bavarian Nordic Research Institute until 2001 as project manager, at the Viennese Veterinarian University and at Austrianova, Vienna, from 2001 to 2009, as coordinator of research liaising between the company and the university, and as operative head of the Christian Doppler Laboratory for Gene Therapeutic Vector Development.

French Muscular Dystrophy Association

AFM was created in 1958 by a group of patients and their families. Its objective is to win the fight against neuromuscular and other rare diseases and reduce the disabilities that they cause. It provides care and support for patients and is a leading advocate for patients with rare diseases.

With funds collected in an annual French Telethon, AFM is committed to the development of innovative therapies resulting from progress in genetics and in partnership with actors of both public and private sector. The mission of the AFM Scientific Department is to accelerate translational research and support of scientific projects aiming at finding treatment for neuromuscular diseases.

AFM has created and directly supports three major research centers:
- Genethon, a non-profit biotech developing gene therapies for rare diseases
- The Myology Institute, a center for muscle expertise encompassing diagnosis and patient care, research and education
- I-Stem, a research institute for stem cells
Infrastructure in Translational Medicine

The goal of EATRIS, European Advanced Translational Research InfraStructure in Medicine, is to provide a highly productive research infrastructure to enable a faster and more efficient translation of basic biomedical research discoveries into new innovative medicinal products. To achieve this, EATRIS engages leading translational research centres and hospitals to provide key preclinical and clinical facilities as well as translational expertise necessary to support the development of new preventive, diagnostic or therapeutic strategies. Unmet medical needs in the most important disease areas and fields of research as well as in rare diseases will drive EATRIS’ development policy.

The EATRIS Translation Centres

The EATRIS Translation Centres will specialise in products such as diagnostics, small molecule drugs, biologics, vaccines or advanced therapy medicinal products like cell therapies and ensure that their core expertise covers the entire development chain.

The unique package of infrastructure and services for scientists will consist of:
- State-of-the-art facilities covering the entire development chain from validation facilities, tracer centres, compound libraries, GMP etc. to research hospitals,
- Expert knowledge in fields such as regulatory issues and product development and
- Training programmes for scientists as well as technicians and nurses.

EATRIS Services

EATRIS supports projects from discovery (Proof of Principle) to clinical trial (Phase I/IIa). The projects will be selected on a competitive basis and will be reviewed regularly regarding their potential of a successful development. From the beginning a project manager experienced in product development will guide the whole process together with a multidisciplinary team. Professional management for each translational project will ensure that quality is maintained and development proceeds in a timely way.
EATRIS acts as one

The supply of research support by EATRIS is harmonised, facilities for research are largely complementary. The central management “EATRIS Coordination & Support” serves as an entrance portal for external scientists and other customers (“one door”). Close interaction with industry will ensure a smooth and efficient commercial take-up of EATRIS products.

One Stop Shop Model

The central management will serve as an entrance portal for the EATRIS services. According to their core expertise EATRIS Centres will offer services focusing on a certain disease or product. Possible disease/product mixes are shown exemplary in the graph.

EATRIS Time Frame

Currently, EATRIS is in the Preparatory Phase. At the end of 2010 it will enter the Implementation Phase (2011-2015) during which the different EATRIS Translation Centres will initiate the first user projects to phase in the operation and gradually expand their capacities, leading to the establishment of full coverage of the necessary technological facilities. By 2016, EATRIS will be fully operational and offer support on a regular basis. It will be an innovation core for new diagnostics and therapies, being attractive for both researchers and industry.

EATRIS Scientific Partners

- Atomic Agency Commission (CEA), France
- Centre for Translational Molecular Medicine (CTMM), Netherlands
- German Cancer Research Centre (DKFZ), Germany
- Helmholtz Centre for Infection Research (HZI), Germany
- Imperial College London, UK
- Institute for Molecular Medicine Finland (FIMM), Finland
- Istituto Superiore di Sanità (ISS), Italy
- Karolinska Institute (KI), Sweden
- University Hospital Vall d’Hebron (FIR-HUVH), Spain
- University of Copenhagen, Cluster for Molecular Imaging (CMI), Denmark
- University of Oslo (UiO), Norway

Goals of EATRIS

EATRIS aims to facilitate that more innovative approaches from academic research find their way to healthcare applications. The medical need and the wellbeing of the population is the driving force for EATRIS developments. By linking basic and clinical researchers and creating a true cross-disciplinary environment, EATRIS will support and advance the translational research culture in Europe. EATRIS will take up promising discoveries across Europe and will increase significantly the number of high-potential translational projects. At the same time, EATRIS “de-risks targets for industry” as drug candidates from academia will be more advanced on the translational path and developed following high quality standards.

EATRIS will strengthen the European biomedical research and health industry and will bring real clinical benefit to patients.
EATRIS Centres

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