Appendix C-3

Biographies of chairs, speakers and panellists

All session chairs, speakers and panellists were invited to prepare a short biography to be included in the information pack given out on the day of the conference and in the report on the conference.

The biographies are listed in this appendix in alphabetical order.

Title: Ms **Name:** Helena Paula Correia Beaumont

Job title: Clinical Trials Department Director

Affiliated to: INFARMED

Represents: INFARMED

Sector: National Competent Authority

Biography:

Currently responsible for the Clinical Trials Department in INFARMED, takes part in EMEA and EC working groups, collaborating in the CT regulatory framework implementation since 2001. Graduated in Biology, holds post graduations studies in Pharmacoepidemiology and Bioethics. Training and experience in GCP monitoring and quality assurance and in biomedical research.

Title: Dr **Name:** Chantal Belorgey

Job title: Head of Division on Evaluation of Special Status Medicinal Products and Clinical Trials

Affiliated to: Afssaps, France

Represents: NCA – Head of Medicines Agencies/Clinical Trial Facilitation Group (CTFG)

Sector: National Competent Authority

Biography:

- Medical doctor
- Master degree in pharmacology
- Many years in Afssaps, France, involved in the assessment of clinical trials and compassionate use
- Head of the Clinicals Trials Division in Afssaps, France.
- France representative in the ad-hoc CT experts group and in the CTFG.
- Co rapporteur on European Guidelines (mainly CTA and Susars reporting guideline).

Title: Dr **Name:** Pierre-Henri Bertoye

Job title: Associate Director of Inspectorate **Affiliated to:** AFSSAPS (C.A., France)

Represents: GCP inspector Working group (group of E.U. GCP inspectors)

Sector: National Competent Authority: GCP inspection

Doctor in medicine, Master's Degree in Computer Sciences.
13 years at Afssaps, France, involved in non clinical study, pharmacovigilance and clinical trial inspection.
Now Associate Director of the Inspectorate at Afssaps
Member of the GCP and Pharmacovigilance Inspector Working group,
Member of the ad hoc Working Party on Guidance documents / Directive 2001/20/EC

GCP Inspectors Working Group (GCP IWG)

The GCP inspector group was established by the EMEA, within the framework of the powers of the EMEA. This group has regular meetings (quarterly), published its mission statement and objectives in 2004 and is mentioned in the guidelines on recommendation on inspection procedures, Volume 10 Chapter IV.

As i) this group has regular meetings ii) deals with topics and procedure within but also outside the strict framework of powers of the EMEA, new name, mandate, objectives and rules of the group were adopted at the Head of Medicines Agencies in Lisbon in July 2007.

Meetings of this group are chaired by a representative of EMEA inspections Sector or delegate. Dr Fergus Sweeney chairs this group.

Title: Prof **Name:** Stefan Bielack

Job title: Head of the Department of Pediatric Oncology, Hematology, and Immunology

Affiliated to: Olgahospital, Stuttgart, Germany

Represents: European Science Foundation (ESF)

Sector: Non-commercial sponsor

Biography:

Prof. Stefan Bielack is a pediatric oncologist and head of the Department of Pediatric Oncology, Hematology, and Immunology at the Olgahospital, Stuttgart, Germany. His main scientific and clinical interest lies in the field of bone sarcomas, particularly osteosarcomas. He is chairman of the Cooperative German-Austrian-Swiss Osteosarcoma Study Group COSS and project leader of the European and American Osteosarcoma Study EURAMOS1. Prof. Bielack is Vice President of the European Musculo-Skeletal Oncology Society EMSOS and board member of the German Society for Pediatric Oncology and Hematology GPOH. He also serves on the editorial boards of the *Journal of Clinical Oncology* and of *Cancer Treatment Reviews*.

Title: Dr. (MD, MPH, PhD) **Name:** Francois Chapuis

Job title: Coordinator, French Sud-Est Inter-Regional Ethics Space

Affiliated to:
Hospices Civils de Lyon, France
Claude Bernard University, Lyon, France
French National Confederation of Research Ethics Committees

Represents:
EUREC (European Network of Research Ethics Committees)

Sector:
Research Ethics Committees

Biography:

Researcher and teacher in Public Health and Social Sciences – Methodology in Clinical Research, Epidemiology, and Ethics in Health – at Claude Bernard University in Lyon, and Hospices Civils de Lyon, France, Dr Chapuis is the former President of the French National Confederation of Research Ethics Committees, now coordinator of the EUREC network (European Network of Research Ethics Committees) supported by the European Commission.
He is also Coordinator of the new French Sud-Est Inter-regional Ethics Space, gathering 7 Medical schools and 4 tertiary teaching hospitals, and co-founder of the new INCLEN trust (International Clinical Epidemiology Network).

Title: Dr. **Name:** Dagmar Chase

Job title: Managing Director **Affiliated to:** Clinrex GmbH

Represents: EUCROF (EU CRO Federation)

Sector: Commercial sponsor

Biography:

Dagmar Chase co-founded the CRO GMI in Munich, Germany, in 1983 and developed it into a full service CRO. In 1997, she sold GMI to Kendle, holding a European management position until 2004. In 2004 she founded Clinrex, a training and consultancy firm for GCP and biostatistics. Dagmar Chase is president of the German CRO association BVMA since 2001 and vice president of EUCROF since 2005.

Title: Professor **Name:** Rory Collins

Job title: Professor of Medicine & Epidemiology **Affiliated to:** University of Oxford

Represents: Clinical Trial Service Unit, University of Oxford

Sector: Investigator

Biography:

Rory Collins became co-director, with Professor Sir Richard Peto, of the University of Oxford's Clinical Trial Service Unit (CTSU) in 1985, and BHF Professor of Medicine and Epidemiology in 1996. He has worked extensively on large-scale randomised trials of treatment for heart attacks, other vascular disease, and cancer.

Title: Dr **Name:** Gaby Danan

Job title: Pharmacovigilance Expert **Affiliated to:** Sanofi-aventis

Represents: EFPIA

Sector: Commercial sponsor

Biography:

Gaby L. DANAN, MD, PhD is board qualified in Hepatology and Internal Medicine. Since 1992, he has been a member of CIOMS groups and ICH Expert Working Groups on Clinical Safety as EFPIA topic leader of E2B. He has authored numerous papers and book chapters on definitions and methodology in Clinical Safety and Pharmacovigilance.He is co-chairing with the EMEA the EudraVigilance Expert Working Group.

Title: Dr **Name:** Brian Davis

Affiliated to: Medicines and Healthcare products Regulatory Agency

Represents: CTFG

Biography:

Dr Davis currently works for MHRA on clinical trials policy where he chairs the MHRA/DH Project Group for transposing the Clinical Trials Directives into UK legislation. He is a member of the Commission ad hoc working group on the guidelines for the Directive and chairs the Pharmacovigilance Subgroup of the Clinical Trials Facilitation Group. He also chairs the EMEA EudraCT Telematics Implementation Group and represents the EU on the ICH Developmental Safety Update Report group.
He joined the UK Department of Health in the Medicines Control Agency in 1989 where he was head of the Clinical Trials Unit from 1991 till 2003. He represented the UK on the Council of Ministers working party on the Clinical Trials Directive.

Title: Mr **Name:** Nikos Dedes

Affiliated to: European AIDS treatment group EATG

Represents: Patients and Consumers Organisations Working Party, EMEA

Sector: Patients representation

Biography:

Co-chair of the PCWP Patients and Consumers Working Party of the EMEA since February 2007.

Chair and subsequently supervisor from the board of directors the 'European Community Advisory Board' (ECAB), the advocacy body of the EATG European AIDS treatment group.
With the EATG, I have been involved in the Pharmaceutical Forum set up by DG Enterprise and DG Sanco in the working group on information to patients.

Title: Prof **Name:** Jacques Demotes-Mainard

Job title: ECRIN coordinator **Affiliated to:** INSERM (France)

Represents: ECRIN (European Clinical Research Infrastructures Network)

Sector: Non-commercial sponsors, Investigators

Biography:

Jacques Demotes, MD-PhD, has a background of neurologist and neurobiologist. Since 2004, he co-ordinates the **European Clinical Research Infrastructures Network (ECRIN), supported by FP6, then by FP7 as a European research infrastructure, connecting national networks of clinical research centres and providing support to multinational clinical research in Europe.**

Title: Ph.D **Name:** Mats Ericson

Job title: Director Regulatory Intelligence Europe **Affiliated to:** Wyeth Research, France

Represents: EFPIA (Clinical Trials Topic Group)
Director Regulatory Intelligence Europe

Sector: Commercial sponsor

Biography:

Mats has a background in academic research (molecular biology) and teaching. He has worked the last twelve years in biotech- and pharmaceutical industry. Initially, with the management of industry-sponsored, multi-country trials in rheumatology, infection and oncology. Currently he works in drug regulatory affairs with a European focus. Mats is a member of EFPIA and EBE regulatory affairs groups.

Title: Dr **Name:** Susan Forda

Job title: Executive Director – International Regulatory Affairs

Affiliated to: Eli Lilly

Represents: EFPIA (Scientific Technical Regulatory Policy Committee)

Sector: Commercial sponsor

Biography:

Sue is a PhD pharmacist with an MSc in the Economic Evaluation of Healthcare.
In 1995 she joined the Eli Lilly. She is now responsible for all European, Intercontinental and Japanese regulatory aspects of Lilly's current and future products. She is chair of the EFPIA "Scientific, Technical, Regulatory Policy Committee".

Title: Dr **Name:** Michael Fuchs

Job title:
Managing Director of the 'Institute of Science and Ethics at the University of Bonn and Lecturer at the Philosophy Department, University of Bonn

Affiliated to: European Association of Centres of Medical Ethics (EACME)

Represents: EUREC (European Network of Research Ethics Committee)

Sector: Ethics Committee

Biography:

Since 2002 : Analysis and Evaluation of New Methods of Treatment Foundation (Clinical Research Unit (DFG) „Stem Cell Transplantation and Immunmodulation – Development of Molecular Theraputic Strategies in Pediatrics"

2003: Contractor of the EC-study (science and society) Provision of support for producting a European Directory of Local Ethics Committees

Since 2005 : - Latin American and European Systems of Ethics Regulation of Biomedical Research (EU)
- Life prolongation and deceleration of human Aging _ individual Asse Ssment, Social Consequances, Ethical Analysis and Normative Judgement (MIWFT).

Title: Professor **Name:** Silvio Garattini

Job title: Director

Affiliated to: Mario Negri Institute for Pharmacological Research

Represents: Investigators

Sector: Non-commercial sponsor, Investigator, European Commission

Biography:

M.D. professor of Pharmacology and chemotherapy. Founder and Director of the Istituto di Ricerche Farmacologiche 'Mario Negri' present in 4 Italian localization with 900 people. Author of hundreds of papers in cancerology, mental health, cardiovascular diseases, and drug policy. Former member of CHMP-EMEA, and chairman of the Committee for independent clinical research.

Title: Dr **Name:** Ritva Halila

Job title: General Secretary

Affiliated to: National Advisory Board on Health Care Ethics

Represents: EUREC

Sector: Ethics Committee

Biography:

MD in 1982 University of Oulu, Ph.D. 1985, University of Oulu, 1997 Specialist in Paediatrics, University of Helsinki. From 1999 has been working as the General Secretary of the National Advisory Board on Health Care Ethics. Evaluates international clinical trials regularly in the Sub-Committee on Medical Research Ethics (National Research Ethics Committee of Finland).

Title: Dr **Name:** Christine-Lise Julou

Job title: Manager of Scientific Technical & Regulatory Affairs Department

Affiliated to: EFPIA

Represents: EFPIA

Sector: Commercial sponsor

Biography:

Held different positions in the pharmaceutical industry including, from September 1989 until August 2001, Director of pharmaceutical Affairs, Director Regulatory Affairs Liaison Europe (Rhone-Poulenc Rorer), Director General & Qualified Person Aventis Recherche & Development, Senior Director Global Regulatory Affairs New Thechnologies Aventis & Gencell

Title: Dr. **Name:** Hartmut Krafft

Job title: Head, clinical trials section **Affiliated to:** Paul-Ehrlich Institute

Represents: NCA: Head of Medicines Agencies / Clinical Trial Facilitation Group

Sector: National Competent Authority

Biography:

- Master degree and PhD-thesis at the German Cancer Research Center in Cell Biology and Immunology
- Postdoc. at the European Molecular Biology Lab., Heidelberg and the Inst. of Pathology, Regensburg, Germany
- Many years at the Paul Ehrlich Institute, Germany, involved in the assessment of mono- & polyclonal antibodies in centralised and national marketing authorisation applications, variations and scientific advices as well as in the batch release of sera in Germany.
- Head of the clinical trials section of the Paul-Ehrlich Institute, Germany, responsible for "biological" medicinal products in Germany
  Member of the EudraCT WP, ad hoc WP 2001/20/EC and CTFG
  Chairperson of the CTFG scientific harmonisation subgroup

Title: Mrs **Name:** Georgette Lalis

Job title: Director **Affiliated to:** European Commission

Represents: European commission

Sector: European Commission

Biography:

Mrs Lalis is a Director in the European Commission's Directorate General of Enterprises and Industry (Directorate F). Her responsibilities include the cars industry, the pharmaceutical and medical devices industry, the cosmetics industry, biotechnology and the food industries.
Mrs Lalis joined the European Commission in 1981 and prior to her present job she has held several managerial and senior positions in different sectors of the Institution, like company law, free movement of services, social legislation, and public health. Her previous post as a Director in the Commission was in Maritime Transports. From 2001-2004 she took an unpaid leave from the Commission and returned to Greece where she was CEO of Ktimatologio SA, the company establishing the Land Register of the country. In parallel she was advisor to the Minister of Environment for EU affairs.
Mrs Lalis has studied law at the University of Athens and later had a post-graduate degree in International and European Law at the University of Strasbourg in France.

Title: Mr **Name:** Alan Morrison

Job title: Vice President **Affiliated to:** Amgen Ltd.

Represents: EuropaBio

Sector: Commercial sponsor

Biography:

Alan Morrison is Vice President International Regulatory Affairs & Safety at Amgen. Prior to this Alan was the Head of Global Regulatory Affairs at Celltech and has held a number of senior management positions within Regulatory and Safety in several biopharmaceutical companies.

Alan is a member of a number of trade association committees and expert working groups relating to biotechnology derived medicinal products, including ICH.

Title: PD Dr (MD) **Name:** Detlef Niese

Job title: Head, External Affairs Clinical Development

Affiliated to: Novartis Pharma AG

Represents: EuropaBio, European Biotech Association

Sector: Commercial sponsor

Biography:

Detlef heads the External Affairs Group in Clinical Development since 2003. He held positions of increasing responsibility within Novartis Clinical Research (formerly Sandoz) since 1992 and is a member of the Clinical Research Management team since 1997. Before joining Industry, Detlef headed Clinical Immunology at the Department of Internal Medicine, University of Bonn. Detlef is also a licensed pharmacist and a member of the Faculty of Medicine at the University of Bonn since 1990 where he continues teaching Internal Medicine.

Title: Professor **Name:** Tamás L. Paál

Job title: Director General **Affiliated to:** National Institute of Pharmacy

Represents: Hungary

Sector: National Competent Authority

Biography:

Graduated in pharmacy, postgraduated in drug control and chemical engineering he worked 11 years for the Hungarian pharmaceutical industry then joined the National Institute of Pharmacy. He is the Head of the agency (with an 8.5 months long break) since 1984. He is also part-time University professor teaching regulatory affairs.

Title: Dr **Name:** Birgitta Pettersson

Job title: MD, PhD, Senior expert, Assessor

Affiliated to: Medical Products Agency, SWEDEN

Represents: NCA/Clinical Trial Facilitation Group

Sector: National Competent Authority

Biography:

Medical doctor and PhD thesis at the Division of Oncology, University Hospital, Uppsala, Sweden

During many years occupied a position as Head of the Gynaecological Oncology Department, Uppsala

Since many years senior expert at Medical Products Agency, Sweden, assessing mostly trials in the oncology field and involved in scientific advice

Member of Ad doc WP 2001/20/EC and CTFG

Title: Dr **Name:** Monique Podoor

Job title: Director Coordination Centre **Affiliated to:** EORTC

Represents: EORTC

Sector: Non-commercial sponsor

Biography:

Long-lasting experience in clinical development activities in the pharmaceutical industry, consultant to the Belgian health authorities and Belgian pharmaceutical sector on implementation of the Directives, director of the EORTC coordinating centre since 2006.

Title: Dr (PhD) **Name:** John Poland

Job title: Senior Director, Regulatory Policy **Affiliated to:** Covance

Represents: ACRO (Association of Clinical Research Organizations)

Sector: Commercial sponsor

Biography:

John has worked in Regulatory Affairs since 1979. Formerly with Ciba-Geigy (now Novartis), he joined Covance in 1988 to establish the European regulatory submissions function, and has personal experience of clinical trial applications across Europe for over 50 products. Currently, John is responsible for regulatory policy and advises Covance's project teams and sponsors on regulatory matters. John has been a member of ACRO's EU and Global Issues Working Group since 2004.

Title: Mr **Name:** Octavi Quintana Trias

Job title: Director **Affiliated to:** European Commission

Represents: European Commission

Sector: European Commission

Biography:

Octavi Quintana Trias is Director for Health Research at the European Commission's Directorate-General for Research and Technology Development.

His is an MD MPH specialist in critical care. He has worked as attending physician in an intensive care hospital unit for eight years. He served as director of the Regional Hospital of Malaga in Spain and later worked as senior advisor at the Spanish Ministry of Health.

He is a former director of international affairs at the Ministry of Health and Consumer Affairs in Spain, and a former president of the Spanish Society on Quality Assurance, the Steering Committee on bioethics at the Council of Europe, and former vice-president of the European Group of Ethics at the European Commission.

Doctor Quintana has acted as a health coordinator in humanitarian crises.

Title: Mr **Name:** Andrea Rappagliosi

Job title: Vice President Health Policy & Market Access

Affiliated to: Merck Serono International

Represents: EuropaBio

Sector: Commercial sponsor

Biography:

Andrea Rappagliosi began his career in the early eighties, first in the Italian Government as a member of staff for the State Undersecretary of the Treasury, then in the Italian Senate focusing on drafting of legislative texts, comparative legal studies and public budget analysis.

In 1992, he joined The Ares-Serono Group as Head of Institutional Affairs in charge of the Rome and Brussels offices. From 1995 to 1999, he was Public Affairs Director at Baxter Healthcare. In 1999, he returned to Serono, today Merck Serono, as Vice President Health Policy & Government Relations.

He is a member of the European Commission's High Level Pharmaceutical Forum representing EuropaBio (European Association for Bioindustries). He is a Board Member of the European Platform for Patients Organizations, Science & Industry (EPPOSI) and represents the Company on many EU and international trade associations including EuropaBio, EFPIA and IFPMA.

Title: Mr **Name:** Rui Santos Ivo

Job title: Administrator **Affiliated to:** European Commission

Represents: European Commission

Sector: European Commission

Biography:

R. Santos Ivo joined the European Commission in 2006 as Administrator at the Pharmaceuticals Unit, Directorate General for Enterprise and Industry. His responsibilities include development of pharmaceutical legislation, the areas of clinical trials and information to patients, EU telematics, relations with the European Medicines Agency, Member States and the Council of Europe, and international Regulatory Dialogues with third countries such as China, India and Russia.
Prior to his present job he was President of the Portuguese Medicines Regulatory Agency (INFARMED), Member of the Management Board of the European Medicines Agency (EMEA) and Chairman of the European Union Heads of Medicines Agencies Management Group. Between 2000 and 2002 he worked as Administrator at the Directorate of the EMEA. He has been a hospital pharmacist before joining INFARMED in 1993.
R. Santos-Ivo holds a degree in Pharmaceutical Sciences from the University of Lisbon since 1987. He received post-graduate education on Health Law, Pharmaceutical Medicine, Regulation and Health Management from the University of Lisbon, the University of Basel, the London School of Economics and Political Science and the Portuguese Catholic University. He is a specialist in hospital pharmacy and pharmaceutical regulation by the Portuguese Pharmaceutical Society.

Title: Mr **Name:** Fernand Sauer

Job title: Honorary Director General **Affiliated to:** European Commission

Represents: personal views

Sector: European Commission

Biography:

Member of the French High Council for Public Health, he recently contributed to a review on the European and Developing Countries Trials Partnership.
He was the first Executive Director of the EMEA (1994 to 2000) and then Director for public health at the European Commission until 2005.

Title: Prof. Dr. **Name:** Patrick Schöffski

Job title: Head of the Department of General Medical Oncology, University Hospitals Leuven. Head of the Laboratory of Experimental Oncology, Catholic University Leuven

Affiliated to: University Hospitals and Catholic University Leuven**,** Herestraat 49,
B-3000 Leuven

Represents: non-commercial sponsors as Secretary General of the European Organization for Research and Treatment of Cancer (EORTC)

Sector: Non-commercial sponsor

Biography:

Prof. Dr. Patrick Schöffski, M.D., M.P.H studied medicine until 1990 and Public Health. He received the degrees Doctor of Medicine, Master of Public Health and Professor of Internal Medicine at Hannover Medical School. He is a board-certified internist, haematologist and oncologist.
He joined UZ and KU Leuven in May 2004.
Main scientific interest: the treatment of solid tumours and lymphomas.
Clinical research activities: new drug development in oncology, including pharmacological, phase I and early phase II studies.

Title: Prof. Dr **Name:** Dominique Sprumont

Job title: Professor of Health Law at the Law Faculty of the University of Neuchâtel (Switzerland).

Affiliated to: Institute of Health Law of the University of Neuchâte

Represents: EUREC (European Network of Research Ethics Committee)

Sector: Ethics Committee

Biography:

Founder of the Institute of Health Law of the University of Neuchâtel. Expert in the field of patient's rights and public health law. He participates at continuing education programs for Ethics Committees' members, healthcare professionals and lawyers at the Swiss and European levels. Since 1994, he is involved in the organisation and conduct of training programmes for Research Ethics Committees members in Switzerland. Since 2006, he coordinates a project supported by the European Union to provide e-learning and e-resources on research ethics and regulation in Africa (www.trree.org).

Title: Professor **Name:** Kent Woods

Job title: Chief executive **Affiliated to:** MHRA

Represents:

Sector: National Competent Authority

Biography:

Chief Executive at the MHRA since January 2004. Previously Director of the NHS Health Technology Assessment Programme (1999-2003) and Regional Director of R&D, NHS Trent (1995-1999). A clinical pharmacologist by training with experience as an investigator in large-scale cardiovascular trials in the NHS setting.