



XII FORESIGHT TRAINING COURSE

INNOVATIVE MEDICINE AND RESEARCH: ETHICAL, LEGAL AND REGULATORY ISSUES

27th September 2019
TOULOUSE, FRANCE

7th Conference of the European Association of
Health law

Room Pèlerins, Hotel Dieu St. Jacques - 2 Rue
Charles Viguerie



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Presentation

The workshop “**Innovative medicine and research: ethical, legal and regulatory issues**” is organized as Foresight Training Course by Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus in Toulouse (France) at Hotel Dieu St. Jacques on September 27, 2019. It will be held within the 7th European Association on Health Law (EAHL) Conference “Innovation & Healthcare – New challenges for Europe”, supported by the Council of Europe.

Emerging technologies in genetics, pharmacogenetics, genomics, advanced therapies as well as ICT applications represent today the most advanced tools incorporated in the drug discovery and research & development process used for producing the largest part of the innovative medicines.

Thus, regulation and guidance have to be continuously adapted and updated to guarantee clinical benefits, economic and health outcome improvements, as well as the respect of fundamental and patient rights.

Legal, ethical and regulatory issues of innovation in medicine and healthcare will be analysed within this workshop.





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AGENDA

13.30 Welcome speeches

A. Ceci, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus (Italy)

A. Altavilla, Espace Ethique PACA-Corse/AP-HM, European Association of Health Law (France)

L. Lwoff, Council of Europe (France)

13.45 INTRODUCTORY SESSION

Models of Governance for Innovation in Medicine and Health Research

S. O'Sullivan, Royal College of Surgeons (Ireland)

14.00 SESSION I - Innovative medicine and research

Chairman

T. Minssen, Centre for Advanced Studies in Biomedical Innovation Law (CeBIL) - University of Copenhagen (Denmark)

14.00 Access to Personal Data for Scientific Research in the perspective of innovative medicines

J. Herveg, University of Namur (Belgium)

14.15 Legal and Regulatory issues dealing with paediatric specificity in the EPTRI (European Paediatric Translational Research) framework

O. Tzortzatos, Biomedical Research Foundation of the Academy of Athens (Greece)

14.30 Intellectual Property Protection of Genetic Material and Information in the Pharmaceutical Sector? - Legal Questions on Genetic Material and Genome Sequencing between Innovation, Protection and Sharing

C. Seitz, University of Basel for Life Sciences Law (Switzerland), University of Bonn's Centre for the Law of Life Sciences (Germany)

14.45 Break

15.00 SESSION II - Access to health care and innovation

Chairman

J. Cayon De Las Cuevas, University of Cantabria (Spain)

15.00 Health Technology Assessment (HTA) and access policies

V. Stühlinger, University for Health Sciences, Medical Informatics and Technology – UMIT (Austria)



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15.15 Machine Learning Systems applied to health data

F. Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus (Italy)

15.30 Exploring solutions to foster ATMP's development and access to patients in Europe

V. Salvatore, University of Insubria (Italy)

15.45 SESSION III - Empowerment and patients' rights in innovative healthcare

Chairman

T. Goffin, Ghent University (Belgium)

15.45 Orphan medicinal products and health budgets: our role as patient advocates

F. Houyez, Eurordis (France)

16.00 Health vulnerability and the European framework on access to orphan medicines

E. Gennet, INSERM UMR 1027, University of Toulouse (France)

16.15 Discussion and conclusion

Chairman

E. Bosone, SIARV (Italy)

A. Altavilla, Espace Ethique PACA-Corse/AP-HM, European Association of Health Law (France)



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SPEAKERS' LIST

ANNAGRAZIA ALTAVILLA



Lawyer and former Professor at Aix-Marseille University, Annagrazia ALTAVILLA is responsible of International Relations of Espace Éthique PACA-Corse (Bioethics Research Centre AP-HM/Aix-Marseille University – France). As French representative in the board of Directors of the European Association of Health Law, she is also co-organizer of the 7th EAHL Conference.

As legal advisor and researcher, she has developed a long-standing experience in the field of Health Law and Bioethics. Annagrazia ALTAVILLA is expert/legal advisor of several EU/IMI founded projects (GRIP, RESPECT, DEEP, GAPP, TEDDY, EMIF, SMART, EPTRI, ARISE).

As expert in ethics and patient rights, she was appointed by the European Commission as member of the European Medicine Agency (EMA) Paediatric Committee for three years. She was also member of the (EMA) Working Group for Third Countries Clinical Trials, as well as rapporteur of the *“Reflection paper on ethical and GCP aspects of clinical trials conducted outside of the EU/EEA”*.

Annagrazia ALTAVILLA is author of a book and about 50 publications in national and international journals. Speaker invited in more than 60 conferences in 15 countries as well as in European Institutions (European Commission, European Parliament, European Medicine Agency, Council of Europe), she has also lectured in Italian, French, Spanish, Belgium and Polish universities. She was member of the scientific/organization committees of several international conferences and courses and of the European School in Health Law and Bioethics (2006-2016).

After having obtained LL.M in Health Law in Italy and in France she was awarded a PhD in Sciences of Life and Health /Ethics (Robert Schuman Foundation fellowship) and an HDR (*“Habilitation à Diriger les Recherches”*) in France. She completed her education by an Executive Programme on Negotiations at Harvard Law School.

FEDELE BONIFAZI



Biomedical Engineer, Post-Graduate Master's Degree in Health Technology Assessment and Management. Gianni BENZI Foundation President and Head of the IT & Research laboratory, designing patient registries, platforms, databases and other tools to support research activities implementing innovation.

Person in charge for HTA-Thal, the Italian multiregional Thalassemia registry, collecting and storing clinical, economic and epidemiological data from around 2,000 Haemoglobinopathies patients in Italy. Member of European Network for Rare and Congenital Anaemias (ENERCA).

Member of the HTA Working Group in the Apulia Region Health Agency.



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Project manager in EU and national research projects (including the EU Networks of Excellence FP6 TEDDY and FP7 GRiP). He is co-lead of the work package “Data coordinating centre and data quality standard” within the Horizon 2020 connect4children (c4c) project, aimed at creating systems, tools and standards to enhance quality, utility, reusability and uniformity of the data collected during paediatric clinical trials. He is also coordinator of the African Research and Innovative Initiative for Sickle cell Education: Improving Research Capacity for Service Improvement (ARISE) project, aimed at creating technological and scientific expertise and tools for promoting best practice in Newborn Screening, diagnosis and treatment of Sickle Cell Disease through an international staff exchange programme.

ENRICO BOSONE



Since January 2015 he is the President of SIARV (Italian Association of Regulatory Activities, Access and Pharmacovigilance), the non-profit Italian Association of regulatory professionals. He started his collaboration with SIAR in 2004, as SIAR Managing Board and Editor SIAR NEWS. He also worked as Director of patient access European policy at Celgene between 2015 and 2016.

Previously, he was director of the Regulatory and Access department of Celgene in Italy and, between 1990 and 2008, of Dompè Group.

Speaker in more than thirty conferences-workshop regarding the regulatory field. Lecturer in several Masters in Regulatory Affairs in the University of Milan, Rome, Chieti and Pavia. Author of several patents, scientific and regulatory papers.

ADRIANA CECI



Former President of Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, President of the Scientific committee of INCIIPIT, the Italian Network of paediatric research and funder member of TEDDY (Task-force in Europe for Drug Development for the Young-EU FP6) still running as Network of excellence for paediatric research, participant in many research projects at national, European and international level. She is also Scientific Counsellor of the Thalassaemia Foundation ‘L. Giambrone’ Board.

Former Professor of Paediatrics at Aldo Moro University of Bari, PhD in Paediatrics and PhD in Clinical and Laboratory Haematology, she also lectured in many universities in the field of Paediatric and Regulatory Sciences. She is member of the Paediatrics and Pharmacology Italian Societies and has been in the Board of the Italian Medical Oncology Association and Group leader in the Italian Paediatric Hematology and Oncology Association.

Former member of the Italian Ministry of Health - Commissione Unica del Farmaco-, “Commissione Nazionale del Sangue”, “Commissione per la Sperimentazione Clinica” -she was also Coordinator of the “Gene Therapies” Committee of the Biotechnology and Biosecurity Committee at the Italian Prime Minister’ Office as well as member of the CONI Antidoping Committee. She was also member of the “Commissione Farmaco e Bambino” appointed to Agenzia Italiana del Farmaco (AIFA) and of the “Comitato Prezzi e Rimborsabilità”



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of the Italian Ministry of budget (CIPE) as well as of the Paediatric Committee at the European Medicine Agency (EMA).

Former member and Vice-President of the “Commissione Sanità” of the Italian Parliament, she was also member of the European Parliament where she founded the EU Parliamentary Inter -Group on Health that she coordinated for 5 years.

She is referee of several international journals and author of more than 130 indexed publications mainly dealing with orphan drugs, paediatrics, regulatory issues.

JOAQUIN CAYON DE LAS CUEVAS



Prof. Dr. Joaquin Cayon-De las Cuevas is Director of the Research Group on Health Law and Bioethics at IDIVAL, and associate professor of health law at the University of Cantabria in Santander, Spain. He holds a PhD in Law with a doctoral thesis on the providing of healthcare according to consumer law. He is combining his academic activities with the legal advice as the head of the Legal Advisory Service at the Health Ministry of the Government of Cantabria.

Joaquin is a member of the Board of Directors of the European Association of Health Law and also serves as Coordinator of the Executive Board of the Ibero-American Health Law Network. Has an international expertise in lecturing, networking, and researching on health law issues, taking into account a multidisciplinary and comprehensive approach. Long teaching and research experience with a wide list of publications (books, chapters and peer-reviewed articles) and oral presentations as a guest speaker in different Latin-American, and European universities. Also has an extensive practical experience in preparing drafts on legal rules regarding healthcare issues for different countries. He is also taking part of the advisory board of different Spanish, Italian, Brazilian and Polish law journals.

His research activities are focused on different health law topics such as the patient-consumer approach, patients’ rights, healthcare systems, AI and big data, healthcare mediation, waiting lists, medical liability, reproductive technologies, and end-of-life decisions. He is currently taking part of the Jean Monnet Health Law and Policy Network funded by the European Commission (2018-2020).

ÉLOÏSE GENNET



Trained in law, specialized in health law, Eloïse Gennet did an interdisciplinary and international PhD in law at the University of Aix-Marseille (France) and in bioethics at the University of Basel (Switzerland). She received the 2019 PhD prize from the French Association of Health Law, as well as the 2018 PhD prize from the legal faculty of Aix-Marseille University in European law for her thesis entitled “Vulnerable people and clinical trials. Reflexions in European law”. She is thus specialized in the fields of health law, bioethics, European law, research ethics as well as on the concept of vulnerability.



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During her PhD, Eloïse Gennet has gathered valuable experience, outside academia, in international organisations, in the pharmaceutical industry and in the hospital setting, notably thanks to a five months traineeship at the Bioethics Unit of the Council of Europe (Strasbourg), a four months internship at the Espace Ethique Méditerranéen (AP-HM, Marseille) or thanks to a year-long mentoring program between the University of Basel and Novartis. She has also worked as a research assistant both at the Institute for Biomedical Ethics of the University of Basel and at the Centre for International and European studies and research at the University of Aix-Marseille.

Eloïse Gennet is currently working as a post-doc at the French national institute for health and biomedical research (INSERM) and is involved in two H2020 projects (CINECA and EASI-Genomics), both of which are mainly related to the European protection of health and genomic data and on data sharing in research, within and outside of Europe.

JEAN HERVEG



Jean Herveg holds a Law Degree from the University of Louvain. He is a member of the Brussels Bar (1993). He has been a researcher at the Centre de Recherche Information, Droit et Société (Université de Namur,) since September 1, 2000. He gave the Medical Law and ICT course from September 2005 to August 2011. Then, he taught the course "Privacy: cross-perspective on technological innovations" with Professor Jean-Noël COLIN (2011-2014).

He gives an introductory course on data protection in the INFOSAFE continuing education programme since 2007 and in the DATASAFE continuing education programme since 2016.

From 2010 to 2017, he gave an introductory course on data protection as part of the MIAGE Master's degree (Computer Science & Innovation), a continuing education course organised by the University of Nancy and the Luxemburg Institute of Science & Technology.

Jean's research activities focus on the protection of privacy in general and on the protection of personal data concerning health in particular, as well as on eHealth products and services.

He is the author of numerous publications, reports and communications on privacy, data protection and e-Health (over 180). He has participated in numerous research projects at Belgian and European level in this field. He is in charge of the LIS (Liberties & Information Society) Department since 1 September 2018.

FRANÇOIS HOUÏEZ



François Houïez is working at the European Organisation for Rare Diseases EURORDIS where he is Director of Treatment Information and Access. He has always been working as a patient advocate since the early 90s, first in the HIV/AIDS advocacy, and in rare diseases since 2003.

He pioneered patient advocacy with the European Medicines Agency as part of the first patients' delegation that engaged dialogue with the Agency back in 1996.



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He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA). He also represents EURORDIS in the HTA Network, and he has been involved in EUnetHTA activities since 2010.

His expertise includes Community Advisory Boards, compassionate use, drug repurposing, involvement of patients in regulatory and HTA activities, drug shortages, pharmacovigilance, marketing authorisation, HTA, pricing and reimbursement, cross-border care.

He is one of the trainers at EURORDIS Summer School on clinical development. François is also a patient.

TOM GOFFIN



Prof. dr. Tom Goffin has obtained a master in law and a doctor in law (medical law) from the Catholic University of Leuven (Belgium), where he started his profession experience as a research assistant in the Centre for Biomedical Ethics and Law of the Faculty of Medicine (2006-2012).

From 2012 until 2018 he worked for the legal service of the National Council of the Belgian Order of Physicians. He is also guest professor at the Catholic University of Leuven and the University of Brussels (VUB).

Since August 2014 until January 2019 he was project manager for the reform of the health professions regulation in Belgium. For this project he consulted several stakeholders in the field of health policy in Belgium. Based on these interviews and literature research he made a framework of a new health professions regulation in Belgium which was presented to the public on October 28th 2016.

Since February 2019 he is full time professor in health law at the Ghent University.

LAURENCE LWOFF



Mrs Laurence LWOFF holds a MSc. in reproductive physiology from the University of Paris VI – Jussieu (France). She then obtained her degree in agronomy from the Institut National Agronomique Paris-Grignon (France) in 1986 and received her PhD in molecular biology in 1989.

She joined the Council of Europe in 1991, where she was entrusted with the responsibilities of the Secretariat of the Conventions concerning the use of animals in agriculture and science, in the Directorate of Legal Affairs. In 1999, her responsibilities were extended to biotechnology. She was the Secretary of the International Conference of the Council of Europe on Ethical Issues Arising from the Applications of Biotechnology (Oviedo, Spain, May 1999). In 2002, she joined the Bioethics Department where she has been responsible in particular for the activities on human genetics and on the protection of the human embryo and the foetus. She was the Secretary of the Group in charge of the elaboration of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes.

Since 2012, she is the Head of Bioethics Unit in the Human Rights Directorate, and Secretary of the Committee on Bioethics (DH-BIO), intergovernmental committee in charge of the activities on the protection of human rights in the biomedical field, at the Council of Europe.



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TIMO MINSEN



Timo Minssen is Professor of Law at the University of Copenhagen (UCPH) and the Founding Director of UCPH's Center for Advanced Studies in Biomedical Innovation Law (CeBIL). He specializes in the interface of Intellectual Property, Competition and Regulatory Law with a focus on new technologies in the health & life sciences, such as gene editing, AI and data-driven medicine. His studies involve a plethora of legal issues emerging in the lifecycle of biotechnological and medical products and processes - from the regulation of research and incentives for innovation to tech transfer and commercialization.

At UCPH he leads several large interdisciplinary research projects in synthetic biology, precision medicine and research infrastructures. At present, he is the PI and grant holder of a large research program in biomedical innovation law, funded by the Novo Nordisk Foundation. Anchored in Copenhagen it involves leading international core partners, such as Harvard Law School, Harvard Medical School, as well as the Universities of Cambridge and Michigan. Timo has also been the legal expert advisory board member of EU Commission studies of the pharmaceutical sector. He is steering committee member of the Danish Association for the Protection of Industrial Property, scientific advisory board member of the Copenhagen Centre for Regulatory Sciences (CORS), and European lead of the Stakeholder Consortium of Social Science Research Centres at the Global AMR R&D Hub, BMBF, Berlin.

Timo holds a German law degree from the University of Göttingen, as well as biotech & IP -related LL.M. M.I.C.L., LL.Lic. and LL.D. degrees from Lund & Uppsala University. He has been Visiting Research Fellow at the Universities of Cambridge & Oxford, Harvard Law School, Chicago-Kent College of Law, and at the Max Planck Institute for Innovation & Competition. Moreover, he was trained in the German Court system and at the European Patent Office.

SIOBHÁN O'SULLIVAN



Prof. Siobhán O' Sullivan is the Chief Bioethics Officer at the Department of Health and is responsible for drafting policy advice and legislative instruments on bioethics related issues. She is also Professor in the Royal College of Surgeons Ireland, where she teaches Healthcare Ethics and Law and is involved in curriculum development. From 2002-2010,

Prof. O'Sullivan was Director of the Irish Council for Bioethics an independent, autonomous body to consider the ethical issues raised by developments in science and medicine.

She is the vice-chair of the European Group on Ethics in Science & New Technologies, an independent, multidisciplinary body advising the European Commission in connection with Community legislation or policies. She also represents Ireland on the Committee on Bioethics in the Council of Europe. She is a former member of the Advisory Council for Science, Technology and Innovation, the Irish Government's high-level advisory body on Science, Technology and Innovation (STI) policy issues.

She received her Doctor of Medicine from Karolinska Institutet, Stockholm in 1998 and hold a Masters in Healthcare Ethics and law and a Masters in Human Rights Law.



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VINCENZO SALVATORE



Vincenzo Salvatore is of counsel at BonelliErede in Milan and leader of the firm's Healthcare and Life Sciences Focus Team.

He is also full Professor of International Law at the University of Insubria – Varese (Italy), where he teaches EU law and International trade law.

Professor Salvatore provides clients with strategic legal counselling on the EU's legal process regulating all aspects of the pharmaceutical industry, including marketing authorization procedures, clinical trials, data protection issues, market access, price and reimbursement, inspections and enforcements.

He is an experienced litigator and routinely represents pharma and medical devices companies before higher Courts in Italy and the Court of Justice of the European Union in Luxembourg in landmark EU law disputes. He is also frequently appointed as pharmaceutical law expert in Court or Arbitration proceedings.

Professor Salvatore served for eight years as Head of the Legal Service and Data Protection Officer at the European Medicines Agency (EMA).

Vincenzo Salvatore authored several books on EU related matters and has extensively published for major EU law journals. He has recently been co-opted as member of the editorial board of the newly published European Pharmaceutical Law Review.

He speaks regularly at academic and professional conferences and routinely serves as a visiting lecturer at universities in Europe and the U.S.

CLAUDIA SEITZ



Legal Advisor, Attorney, Researcher, Lecturer and former Assistant Professor at the University of Basel's Faculty of Law, Claudia Seitz is a Lecturer and Researcher at the University of Bonn's Centre for the Law of Life Sciences as well as the University of Basel's Center for Life Sciences Law (CLSL). Her research focuses on health, pharmaceutical, regulatory, IP and competition law with a special focus on biomedical innovation law and new technologies such as genetic resources, genome sequencing, synthetic biology, precision medicine and digitalization.

As a scientific expert and legal advisor Claudia Seitz is currently working on a study for a project on digital sequence information funded by the German government and has been appointed as a member to the Advisory Board of the German Association for Synthetic Biology (GASB).

She is also a member of the editorial and advisory board of several law journals such as the European Pharmaceutical Law Review (EPRL) and the Europäische Zeitschrift für Wirtschaftsrecht. As a scientific director and advisor to multiple scientific international programmes of the World Intellectual Property Organization (WIPO), the Swedish Patent and Registration Office (PRV), the Indonesian Agency for Agricultural Research and Development (IAARD) and the University of Ghent as well as a Scientific Advisor at the Swiss Federal Administrative Court Claudia Seitz has developed a long-standing practical expertise in IP and regulatory law. As a Counsel at an international life sciences company for many years she gained an in-depth knowledge of life sciences law.



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Claudia holds German law degrees as well as a PhD from the University of Basel (Dr iur), a Postgraduate Diploma and a Master's Degree (M.A.) from King's College London and is admitted to the Bar in Germany. She is lecturer at various Universities and has also significant practical experience in relation to pharmaceutical, regulatory, biotech and innovation law. She is author of several books, commentaries and about 100 publications in national and international law journals as well as a regular speaker in more than 80 conferences at several universities and institutions.

VERENA STÜHLINGER



Verena Stühlinger is data protection officer and senior scientist at the Institute of Public Health, Medical Decision Making and Health Technology Assessment at the Private University for Health Sciences, Medical Informatics and Technology, Austria, where she chairs the institutional review board - Research Committee for Scientific Ethical Questions (UMIT and health university of applied sciences tyrol (fhg) (RCSEQ)).

Verena Stühlinger holds a Doctoral degree in Public Health from UMIT, Austria, as well as a Masters degree in Law from the Law School in Innsbruck and a Masters degree in International Law (LL.M.) from Golden Gate-University, San Francisco. Before she started her position at UMIT in 2004, Verena Stühlinger was working as an Associate in the law offices of James R. Frolik in San Francisco (USA) and at the law firm Greiter, Pegger, Kofler & Partners in Innsbruck (Austria) and passed the Austrian bar exam in 2003.

She teaches (public) health law, medical law, medical negligence (private law), law and ethics in health care and research at all levels (bachelor, master, doctorate). Her current research focus includes (legal and) ethical decision making in the clinical context (clinical ethics committees), ethical and legal frameworks for human research, cross-border healthcare in Europe and the integration of ethical, legal and social issues (ELSI) in HTA. Verena Stühlinger is a board member the European Association of Health Law (EAHL).

OLGA TZORTZATOU



Olga Tzortzatou is a Doctor in Law. Her academic research focuses on the legal and ethical implications related to biomedical research and she has participated in numerous EU funded projects as a legal & ethics scientific advisor (e.g B3Africa, SIENNA project (affiliated with CRB, Uppsala University), EATRIS, 1 and Million Genomes Project, etc.).

Since 2007 she holds a position as a lawyer at the Biomedical Research Foundation of the Academy of Athens (BRFAA).

She is also an external ethics expert at the European Commission DG Research & Innovation, a Member of Democritus University and the Biomedical Research Foundation of the Academy of Athens Research Ethics Committee and an active member of the ELSI BBMRI-ERIC team since 2015.