

# Second plenary meeting of the VolREthics Initiative April 24-25th, 2023 European Commission – Covent Garden building, Brussels, Belgium

## CHAIRPERSONS & SPEAKERS



### **Roberto ABADIE, University of Nebraska-Lincoln (USA)**

I completed my doctoral degree in Anthropology from the Graduate Center, City University of New York, and have postdoctoral training in bioethics at the Mayo Clinic and McGill University. Currently, I am an Assistant Professor at the Department of Anthropology, University of Nebraska-Lincoln. As a trained medical anthropologist my research is at the intersection of anthropology, public health and bioethics. My main concern is how different forms of social stratification, in particular, class, race, and ethnicity, contribute to produce and reproduce health inequalities in marginalized populations and how these factors might place an undue burden in vulnerable subjects participating in biomedical research.

My interest in the protection of research subjects is a continuation of my previous work on healthy paid volunteers enrolled in Phase I clinical trials. *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects*, illustrates how vulnerable subjects can be exposed to disproportionate health risks. An ethnographic study of healthy, paid subjects in Phase I clinical trials in Philadelphia, examines a group of self-defined professional “guinea pigs” who earned their livelihoods as research subjects by testing drugs being developed by the pharmaceutical industry. My monograph received the “Best Book of the Year” award by the Medical Sociological Association, a section of the British Sociological Association.



### **Elisabeth ALLEN, The Global Health Network, Oxford University, (UK)**

Elizabeth is a pharmacist with an Master’s in Public Health and PhD Clinical Pharmacology who is currently Strategic Partnership Lead for The Global Health Network, which seeks to enable equity in health research by improving methods, building careers and sharing knowledge. She previously worked in the UK and South African pharmaceutical and contract research industries before moving into academic clinical research, and until recently led operations for the University of Cape Town’s MRC Collaborating Centre for Optimising Antimalarial Therapy, overseeing clinical trials, individual patient data meta-analyses, and methodology research related to participants’ experiences of clinical research. She is also co-lead for the UK MRC-NIHR Trials Methodology Research Partnership Global Health Working

Group, and teaches and supervises post-graduate students in the fields of pharmacovigilance and clinical trial conduct.



### **Maria-Antonietta ANTONELLI, European Medicines Agency (EMA)**

Maria Antonietta qualified as a biologist at University of Rome La Sapienza in 1995 and holds a Specialisation in Toxicology, a Master Degree in Bioethics and a Master Degree in Clinical Trials. She worked as Study Director/Toxicologist at a Contract Research Organization from 1999 to 2001.

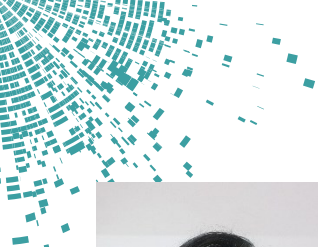
In November 2001 she joined the Italian Ministry of Health and then in 2004 the Italian Medicine Agency (AIFA) where she has worked as a senior GCP senior inspector until September 2008. She has participated in approximately 85 GCP inspections mainly in Italy but also elsewhere in Europe and Africa.

Maria Antonietta joined the European Medicines Agency (EMA) in September 2008 as a Scientific Administrator in the Compliance and Inspection Sector. She is a Senior Scientific Specialist involved in the selection and coordination of the EMA GCP inspections, she provides scientific support to a number

of EMA Working Groups dealing with GCP, Bioequivalence and GLP inspections

She was a Member of the EMA Working Group on Third Country clinical trials; she supported the preparation of the Draft Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA and she was the coordinator of the International Workshop on Draft Reflection Paper on Ethical and GCP Aspects of Clinical Trials in 3rd Countries.





### **Deepa ARORA, CLINEXEL (India)**

Deepa is a physician, with 20 years of industry experience in leadership positions in clinical development and drug safety and risk management. Her experience includes development and execution of clinical development strategy for new chemical entities (NCEs), biosimilars, complex generics and repurposed drugs. Dr Arora has interacted with various regulatory authorities including the USFDA, EMA, MHRA, MEB, Health Canada, TGA for scientific advice, Pre-IND meetings, end of the phase meetings to discuss the clinical development path, clinical trial designs, safety issues and post marketing commitments including post marketing studies and pediatric investigation plan (PIP). Deepa has experience of early phase drug development in Oncology, COVID, Alzheimer’s, Diabetes, infectious diseases, and rare disorders for EU markets. Dr Arora led clinical development programs on new chemical entities,

biosimilars and 505(b)(2) approvals.

In 2019, Deepa founded CLINEXEL Life Sciences Pvt Ltd, a CRO that aims to provide end to end clinical research services to small and mid-size pharma companies for efficient clinical development and approval of NCEs, NBEs, biosimilars and repurposed drugs. CLINEXEL team is working on NCEs, Biologics, Medical Devices and IVDs in early clinical development and late-stage development and they are conducting Phase 1 to Phase 4 clinical trials.



### **Ignasi BELDA, EIT Health ELSI Board (Spain)**

Dr. Ignasi Belda is a professional in life sciences management that has received multiple awards for his companies and managing activities, including the Award Prince of Girona 2014. Belda founded six international biotechnological companies and he sold four of them. During two years he managed, as a CEO, the Barcelona Science Park, a medium sized public company of 18 million euros of revenues and 110 employees. He holds two PhD’s, one in artificial intelligence applied to biomedicine and the other in law & technology. He is professor of Ethics at the Universitat Internacional de Catalunya and is and has been member of several ethics committees.

### **Pierre-Henri BERTOYE, UNICANCER (France)**

### **Calvin BERTRAND, Direction Générale de la Santé (France)**



### **Luc BIGEL, DLA Piper France LLP (France)**

Luc Bigel, Partner at DLA Piper, is an insurance specialist, registered with the Court of Appeal of Paris and Québec Bars advising clients in both litigation & regulatory issues. He has gained particular experience in complex litigations and restructuration’s, including medical liability.

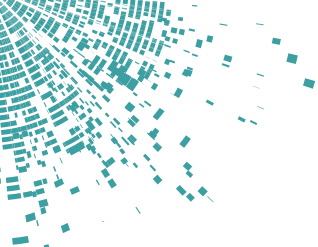


### **Montserrat BLÁZQUEZ-DOMINGO, European and Developing Countries Clinical Trials Partnership, EDCTP2 Programme**

Dr Montserrat Blázquez-Domingo holds a Master’s degree in Biochemistry from the Autonomous University of Barcelona, Spain, and a PhD degree in Cell and Molecular Biology from the Friedrich Miescher Institut (FMI)/University of Basel, Switzerland. As a post-doctoral fellow, her research focused on Biomedical Immunology and Haematology at the European Molecular Biology Laboratory (EMBL-Heidelberg) in Germany and the Erasmus University of Rotterdam (Erasmus-MC) in the Netherlands, respectively. In September 2007, she joined the European & Developing Countries Clinical Trials Partnership (EDCTP-The Hague Office) as Project Officer and since 2015 as Senior Project Officer. At EDCTP, she is the focal person for the malaria portfolio and oversees and monitors a large portfolio of multi-country grants in the area of malaria and HIV/AIDS research conducted in resource-limited settings. In addition, she also manages and oversees calls for proposals, from grant application, management of the peer-review process, etc. to post-award evaluation. Montserrat has a personal interest in clinical research uptake into policy, and access to health innovations in low- and middle-income countries.

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### **François BOMPART, DNDi (Switzerland) & Inserm Ethics Committee (France)**

François Bompert, MD is the Chair of the Access Committee of the Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation based in Geneva (Switzerland).

His has worked for over 25 years in anti-infective medicines and vaccines, with a focus on emerging and developing countries, mostly within the Sanofi pharmaceutical group. His main fields of interest are related with access to care in resource-limited countries, as well as ethical issues in clinical research. His specific interest in ethical issues related with healthy volunteers started with being a healthy volunteer himself in the 1980s, then an investigator and a sponsor of Phase I studies. He initiated the VoREthics initiative with the Ethics Committee of the French National Institute for Health and Medical Research (Inserm), then became a member of that committee in 2022. The VoREthics initiative aims at protecting healthy volunteers from exploitation in biomedical research everywhere in the world.

He received his MD from the University of Angers (France) and trained in Clinical Pharmacology at University College London (UK) and Hôpital Cochin in Paris (France).



### **Nicholas C.W LEOW, National Pharmaceutical Regulatory Agency (NPRA) (Malaysia)**

Nicholas Leow Chun Wei is the Senior Principal Assistant Director at the Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia. He is a pharmacist by profession and holds a Master’s degree in Clinical Research from Cranfield University, United Kingdom. He is currently Head of the Bioequivalence Centre and Ethics Committee Section coordinating and conducting inspections to local and foreign Bioequivalence Centres for listing on the NPRA BE Centre Compliance Programme, and local Ethics Committees for listing under the Drug Control Authority. Prior to joining the agency, Nicholas is a clinical pharmacist at Sibu Hospital, Sarawak and was the Head of the Clinical Pharmacy Services Unit with responsibilities including providing pharmaceutical care to patients

with an area of interest in respiratory medicine, pain management in palliative care and antibiotic stewardship. He joined the agency as an evaluator for investigational products at the Centre of Investigational New Product before taking over the helm of the Investigational Product Safety Section and subsequently the GCP Compliance Section. He has since taken over the current section after the NPRA restructuring in December 2019. Nicholas is a qualified GCP inspector with experience inspecting trial sites, ethics committees, sponsors, contract research organisations and bioequivalence centres both domestically and abroad. Nicholas was also appointed as an independent expert in the Medical Research and Ethics Committee from 2017 – 2019 and is also involved in the publication of various guidelines including the Malaysian Guideline for Good Clinical Practice Inspection, Malaysian Guideline for Phase 1 Unit Inspection and Accreditation Programme and the Malaysian Guideline for Independent Ethics Committee Registration and Inspection.



### **Henri CAPLAIN, Association Française de Pharmacologie Translationnelle (AFPT) (France)**

Dr. Henri Caplain, MD, MSc, is a physician, independent senior adviser in early clinical development, translational pharmacology, and drug safety risk management. He is the current President of the ‘Association Française de Pharmacologie Translationnelle (AFPT) - Le Club Phase 1’ founding member of ‘The European Federation for Exploratory Medicines Development’ (EUFEMED). After 15 years as primary investigator for early phase clinical trials (particularly first-in-human in healthy subjects) and

medical scientific director within an International CRO ‘Aster-Cephac Group’ based in Paris, he joined for 12 years the Sanofi-Synthelabo Research R&D as head of clinical pharmacology and Exploratory, member of the R&D board. He became associate VP, deputy-head of worldwide clinical pharmacology for Sanofi-Aventis R&D, then head of the risk management center of excellence within Sanofi, responsible of all DRMPs and RMPs, and member of the Benefit-Risk Assessment Committee chaired by the Sanofi Chief Medical Officer (CMO).







### **Chun Keat CHEW, Institute for Clinical Research (Malaysia)**

Chun Keat Chew (CK Chew) is the Technical Head for Centre for Clinical Trial, Institute for Clinical Research (ICR), National Institute of Health. He is a pharmacist graduate from University Science Malaysia. Through a collaboration between a phase 1 clinical trial organization and Ministry of Health, he has learned from the expert on the conduct of phase 1 clinical trial at Plymouth, UK and Ahmedabad, India.

He was given the opportunity to be part of the pioneer team to develop a Phase 1 Clinical Trial Unit under Institute for Clinical Research in Hospital Ampang. The unit has conducted many pharmacology studies determining bioavailability of study compound, drug-drug interaction, food-drug effect, drug formulation effect, bioequivalence studies, and phase 2/3 vaccine trials. Most of the trials are healthy volunteer based clinical trials. Knowing the challenges of ensuring the safety of healthy trial participants at national level,

he has worked under ICR together with the local regulatory, National Pharmaceutical Regulatory Agency and other trial sites, to development a national register, National Healthy Research Volunteers Register (NHRVR). NHRVR aims to ensure healthy trial participants safety by having sufficient trial-free period and preventing over-volunteerism.

He has participated in few expert panels and working groups in development of few instrumental guidelines and books, like Malaysian Guideline for Phase 1 Unit Inspection & Accreditation Programme, Malaysian Phase 1 Clinical Trial Guideline, and A Guide to Conducting Clinical Trials in Malaysia.

He has been appointed as Board Member of Medical Research and Ethics Committee (MREC) for the Ministry of Health, Malaysia since 2015. He also helped to develop and enhance the monitoring of pharmacovigilance in clinical research approved under MREC via an online reporting platform for Serious Adverse Reaction (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR). His past working experience as Drug Enforcement Officer, and Regulatory Officer in National Pharmaceutical Regulatory Agency (NPRA) has enabled him to have a better understanding on the fundamental of local Acts and Regulations pertaining to pharmaceutical products.



### **Hervé CHNEIWEISS, President Inserm Ethics Committee (France)**

Hervé Chneiweiss is a neurologist and neuroscientist, MD-PhD, Research Director at the CNRS. He is currently head of the research centre Neuroscience Paris Seine (CNRS /Inserm/Sorbonne University). Trained as a neurologist (movement disorders, neurogenetics), his scientific work was mainly dedicated to the biology of astrocytes and in the recent period their roles in brain tumour origin, progression and plasticity, identifying new metabolic drivers and therapeutic avenues. He has authored more than 170 academic papers (h 53).

He is also involved in bioethics, presently chair Inserm Ethics Committee (IEC) and past-chair of UNESCO International Bioethics Committee, former member WHO advisory committee on developing global standards for governance and oversight of human genome editing and vice-chair of ARRIGE, expert OECD for recommendation 457 on neurotechnology in health. He wrote several books or chapters on bioethics of human embryos, stem cells, genetics and neuroscience.



### **Pierre DEMOLIS, Agence Nationale de Sécurité du Médicament et des produits de santé (France)**

Pierre Démolis is a physician by training and obtained a PhD in clinical pharmacology. After years spent in the University Paris Sud as a senior lecturer and in the corresponding university hospital as a cardiologist, he joined the French Medicines Agency (ANSM) in 2003. He has been working since in the European regulatory system for medicines. From his position at the ANSM, he has represented his agency at the European Agency (EMA), being for ten years the French delegate at the CHMP, the centralized committee in charge of benefits and risks assessments preparing opinions for marketing authorizations and modifications. He is currently the vice-chair of the working party responsible for European scientific advices (SAWP) and the chair of the Oncology Working Party. At a national level he is a scientific and medical advisor near the executive management of ANSM.





### **Lisa DIEPENDAELE, Ethics and Research Integrity Sector, DG Research & Innovation, European Commission**

Lisa Diependaele is a policy officer for the Ethics and Research Integrity Sector of the European Commission. Her work is focused on bioethics and ethics of new and emerging technologies in health research context. In this capacity, Lisa has been involved in the elaboration of policy guidelines, procedures and recommendations for Horizon 2020/Horizon Europe applicants and beneficiaries.

Before joining the Commission in 2020, Lisa was a postdoctoral researcher and assistant academic staff member at Ghent University. She lectured courses in applied ethics and global ethics as well as social and political philosophy. Her research focussed on ethical issues relating to the protection of pharmaceuticals

through patents, data exclusivity and trade secrets, intersections with international investment law, and ethical issues pertaining to the use of algorithms in the context of clinical research and decision-making. Lisa obtained a PhD in Philosophy in 2019, and holds Master's degrees in International and European Law and Moral Sciences (Ethics).



### **Yves DONAZZOLO, European Federation for Exploratory Medicines Development (EUFEMED) and the European CRO Federation (EUCROF)**

Dr Yves Donazzolo is a medical doctor and a clinical pharmacologist. In 1990, he cofounded Eurofins Optimed, a company dedicated to the early clinical development of drugs and health products in Europe with particular expertise in early development studies, from First-into-Human to Proof-of-Concept trials. He has served as Principal Investigator in several hundreds of trials. He is also a doctor in the emergency department of Grenoble University Hospital.

He has been a lecturer in several teaching programs in clinical pharmacology and drug development and is responsible for a Master Module at Grenoble Alps University. He is an active member of the French

Society of Translational Pharmacology (AFPT– Le Club Phase I), where he has served as President for two terms. He has been a founding member of EUFEMED, the European Federation for Exploratory Medicines Development. In addition, he is a member of the French Society of Pharmacology (SFP), the British Pharmacological Society (BPS) and the American College of Clinical Pharmacology (ACCP).



### **Joanna DRAKE, Deputy Director-General, DG Research & Innovation, European Commission**

Joanna DRAKE has been the Deputy Director-General of the European Commission's Directorate-General (DG) for Research and Innovation (DG RTD) since 2021. In this role, she provides overall assistance to the Director-General in the management of the DG, contributing to the definition, coordination and implementation of strategy and policy orientation. She is also Mission Manager for the EU Mission Cancer.

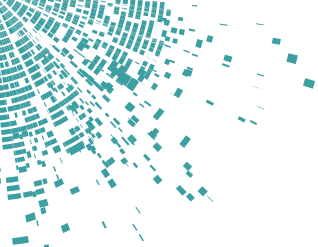
She was previously Deputy Director-General of DG Environment (2016-2021) where she chaired a cross-cutting Task Force spear-heading strategic positions for the DG on (inter-alia) the post-2020 Commission financial framework negotiations, Brexit co-ordination, the urban agenda and the future-proofing of the EU's environmental acquis. Between 2010 and 2015 she was director for SME's and Entrepreneurship in the DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).

During her tenure in DG GROW she also led the Commission's Task Force on The Collaborative Economy, New Business Models And SME's.

By training, Joanna is a doctor of laws from the University of Malta, where she also lectured full time in the Department of European and Comparative Law. She acquired a post-graduate degree in Advanced European Legal Studies from the College of Europe in Bruges, Belgium.

She held various legal and management posts in the private and public sector before joining the European Commission as head of the European Commission Representation in Malta in 2005. She also had a key role in the Malta-EU accession negotiations as member of the Malta-EU Steering and Action Committee.





### **Hélène ESPEROU, Inserm (France)**

Hélène Espérou is a hematologist. She currently heads the clinical research department of the French Institute of health and medical research (Inserm). As such, she assists researchers to insure the doability, the quality and the adapted implementation of their research, and she also guarantees that regulatory texts are respected and that research participants are protected. She is the Inserm sponsor representative of the studies 'governance committees and she leads the exchanges with the stakeholders involved in the trials' running.

As a member of the Steering Committee of Inserm, she participates in the development of the institute's strategic policy in the field of clinical research. In addition, she is committed in the institutional actions of the "science and society" department including the support to the participatory researches. Hélène Espérou has worked for eighteen years as a clinical practitioner at St Louis Hospital. She received a degree in advanced studies in Health economics. For the last fifteen years, she has occupied some different positions in public health institutions, the French Agency of Biomedicine, the French federation of the comprehensive cancer centers (FCCCs). During two years, she held a position at the Cabinet of the Ministry of Health as a technical adviser for Health policies.

### **Maria-Filipa FERRAZ-DE-OLIVEIRA, European Research Council Executive Agency (ERC)**



### **Jill A. FISHER, University of North Carolina (USA)**

Jill A. Fisher, Ph.D., is Professor in the Department of Social Medicine and Center for Bioethics at the University of North Carolina at Chapel Hill. She holds a Ph.D. in Science and Technology Studies, and her research primarily focuses on how clinical trials are conducted and who participates in them as researchers and participants. She has published more than 50 articles and book chapters, and she is the author of *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials* (Rutgers University Press, 2009) and *Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals* (New York University Press, 2020). She also edited the collection *Gender and the Science of Difference: Cultural Politics of Contemporary Science and Medicine* (Rutgers University Press, 2011). More information about Dr. Fisher as well as many of her publications can be found at her website:

[www.jillfisher.net](http://www.jillfisher.net).



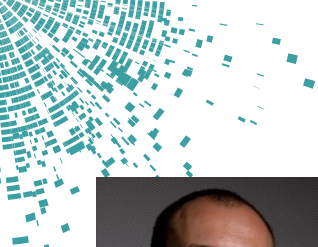
### **Danilo Cesar GALINDO BEDOR, Federal University of Pernambuco (Brazil)**

Associate Professor of the Pharmacy course (2012-current), Professor of the Graduate Program in Pharmaceutical Sciences (2015-current). He held the position of bioanalytical manager (2007-2018) of the bioavailability/bioequivalence center of the Pharmaceutical and Cosmetic Development Center - NUDFAC of Federal University of Pernambuco, was member of the Research Ethics Committee (2013-2022) of the Federal University of. Has experience as a consultant for several pharmaceutical companies in development and validation of analytical methods by HPLC and analytical validation. From 2009 to 2012, he was managing partner of an innovation laboratory in the field of bioanalysis, having participated in phase I and II clinical studies for neglected diseases in the quantification of Sample in Dried Blood Spot. He works in scientific research in Pharmacy, with emphasis on biopharmacy, mainly in the following topics: Pharmacokinetics and bioavailability, Development, and validation of the bioanalytical method (HPLC and LC-MS\MS), bioequivalence studies. As an academic background, graduate at Pharmacy (2004), a master's degree (2007) and a PhD (2011 - Partnership with Université D'auvergne - France) in Pharmaceutical Sciences in Pharmaceuticals and Medicines, all from the Federal University of Pernambuco and a post-doctoral in biopharmaceutical evaluation (biopharmaceutical classification of inhaled products) at the Université de Poitiers - France (2015).

### **Fabrice GZIL, Espace Éthique Ile-de-France (France)**







### **Thomas HINAULT, Inserm (France)**

Thomas Hinault conducted his research in Canada (Montreal Neurological Institute, McGill University) and the United-States (Johns Hopkins University) before joining INSERM and the “Neuropsychology and Imaging of Human Memory” research unit (U1077 Inserm-EPHE-Unicaen, Caen, Normandy). He received the “Théodule Ribot” early career award for his work on the cognitive and brain changes occurring with aging. His work combine advanced neuroimaging methods with thorough cognitive assessment (memory, time perception) to specify the variability across individuals with advancing age and the factors associated with elevated risk of cognitive decline.



### **François HIRSCH, Inserm Ethics Committee (France)**

François Hirsch graduated in immunology from the Pasteur Institute and in Science & Medical Ethics from Paris-Sud University. He spent 30 years at the National Institute for Health and Medical Research (Inserm) holding various positions in scientific research and research administration, including Secretary General of the Ethics Committee and Deputy Director of the Health Technologies Institute. For three years, he was a National Expert seconded to the Governance and Ethics Unit of the European Commission (EC), where he contributed to the organization of the ethical evaluation of the research projects submitted for funding. François Hirsch is currently a member of the Inserm Ethics Committee, Secretary of the Ile-de-France 7 Committee for the Protection of Persons (national registered IRB) and a member of the Board of Directors of the National Conference of CPPs. At the international level, he holds responsibilities as Secretary General of the International Association for Responsible Research In Genome Editing (ARRIGE) and leads the international initiative VolREthics aiming at establishing good practices for research involving healthy volunteers. He is also an ethics evaluator for various European Commission agencies and a member of the European network of research ethics committees (EURECNet).



### **James A. HOUGHTON, National University of Ireland, Galway (Ireland)**

Professor James Houghton is Emeritus Professor of Microbiology at the National University of Ireland, Galway.

A human geneticist by training, he also served as: Head of the Clinical Cytogenetics Unit; Head of the Department of Microbiology; Head of the School of Natural Sciences, etc.

In 2002, he was appointed the Director of the National Diagnostics Centre of BioResearch Ireland.

Professor Houghton has been actively involved in research ethics for over 20 years. He regularly participates in Ethics Screening, Assessment, Checks and Audits on behalf of the European Commission and other Agencies. He also serves on Scientific Panels for national, European and international research funding bodies. He is a member of Irish Ethics Boards and acts as an independent Ethics Advisor on several

EC-supported projects.

In recent years, Professor Houghton has served on several European Commission Working Groups involved in the drawing up of Ethics Guidance Documents for H2020-funded research. These include “How to complete your Ethics Self Assessment”, “Guidance Note on Research on Refugees, Asylum Seekers & Migrants”, “Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects”, “Guidance Note: Informed Consent and Research”. He also contributed to “Identifying Serious and Complex Issues in EU-funded Research.



### **Irakli KHODELI, UNESCO**

Irakli has been with UNESCO since 2006. As part of Bioethics and Ethics of Science and Technology team at UNESCO Headquarters in Paris, he has been facilitating global reflection on ethical issues emerging at the frontier of scientific and technological progress, and supporting international standard-setting to safeguard human rights from the associated risks. He has also led the development of capacity-building initiatives to help countries translate global normative instruments into national policies and action. From 2015 to 2020, he headed the Social and Human Sciences Unit of UNESCO’s Regional Science Bureau for Asia and the Pacific in Jakarta, working with the governments and the civil society in Brunei Darussalam, Indonesia, Malaysia, Philippines and Timor-Leste. Since 2020, he has rejoined UNESCO headquarters to support the elaboration, adoption and the implementation of the Recommendation on the Ethics of AI, the

first ever global instrument in the domain, and to facilitate the work of UNESCO’s global ethics committees: COMEST and IBC.

Irakli’s experience includes his work with the Council of State Governments (USA, 2002-2005) and Open Society Georgia Foundation (Georgia, 2005-2006).





### **Natalie KLEIN, Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (USA)**

Natalie Klein is the Director of the Division of Policy and Assurances for the US Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), where she supports efforts to develop guidance on HHS human research protections regulations. She joined OHRP in 2021 from the US Army Medical Research and Development Command (USAMRDC), where she served as a liaison to intramural research institutes for human research protections issues and helped provide regulatory oversight for USAMRDC-supported research conducted at over 1600 institutions in 67 countries. Dr. Klein received the Department of the Army Superior Civilian Service Award in 2019, in part for her contributions to assessing the ethical, legal, and social implications of emerging technologies. She

earned a doctorate in Brain and Cognitive Sciences in 2011 from the University of Rochester as a Beinecke Scholar and is a graduate of Pomona College.

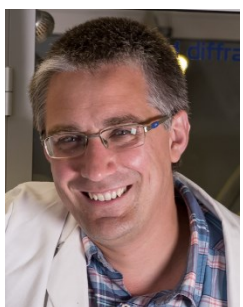


### **Ingrid KLINGMANN, EUFEMED and European Forum for Good Clinical Practice (EFGCP)**

Physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior medical, operational and managerial functions in pharmaceutical industry, CROs and clinical trial sites with focus on clinical trial design and management, ethical and regulatory aspects. Since January 2003 she has her own pharmaceutical development and site management support consulting company.

Dr Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). Her broad professional background as physician with experience in patient care, clinical development, site management, regulatory affairs, clinical research ethics, and patient engagement enables Dr Klingmann to bridge the gaps between the interests and skills of all different stakeholders in medicines development with the aim to develop new patient-relevant treatments more efficiently.

Dr Klingmann is currently also Secretary of EUFEMED, the European Federation of Exploratory Medicines and President of PharmaTrain Federation, the not-for-profit organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences. She also teaches on different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, Germany, University of Basel, Switzerland, and the Université Libre de Bruxelles, Belgium.



### **Simon KOLSTOE, University of Portsmouth (UK)**

Dr Simon Kolstoe is a Reader in Bioethics at the University of Portsmouth, UK, where his work looks at the role of ethics committees and governance structures in promoting research integrity. He chairs research ethics committees for the UK's NHS, Ministry of Defence, and Health Security Agency, and is a member of the specialist "Human Challenge" research ethics committee. He is a trustee of the charity UK Research Integrity Office (UKRIO), the UK adapting author of the popular Epigeum "Research Integrity" course, and an Ethics Associate Editor for Heliyon.

Prior to moving into Bioethics his background is in Biochemistry (PhD, Southampton 2005) with seven years as a post-doctoral research fellow at the Centre for Amyloidosis and Acute Phase Proteins, UCL Medical School. He joined the University of Portsmouth in 2012 as a Senior Lecturer in Biochemistry, receiving a 2014 BBSRC project grant exploring immune proteins involved in complement and DNA vaccination. Following further degrees in Philosophy (BA, Open 2010) and Research Ethics (MA, Keele 2012), he moved to a Senior Lectureship in Evidence Based Healthcare in 2017, and then Reader in Bioethics as of 2021.




### **Carleigh KRUBINER, Wellcome Trust (UK)**

Carleigh Krubiner is the Bioethics Lead at Wellcome, helping the foundation proactively embed ethics throughout their activities and portfolio as they pursue an ambitious new strategy centred around: discovery research, infectious disease, mental health, and health impacts of climate change. She also oversees a portfolio of strategic investments in global bioethics infrastructure and community building, which includes various professional bioethics networks, funded research centres, and global convenings. Carleigh's past research has focused on ethical issues surrounding equity in the development and delivery of health interventions in low and middle-income settings.







Recent work includes approaches to priority-setting for Universal Health Coverage, ethics frameworks for COVID-19 vaccine allocation, the fair and responsible inclusion of pregnant and lactating people in vaccine development and deployment, and the indirect impacts of the COVID-19 pandemic across other areas of health. Her doctoral work explored the ethical dimensions of monetary incentives for health promotion.



### **Nandini KUMAR, Forum for Ethics Review Committees (India)**

Dr. Nandini K. Kumar completed her MBBS and Post Graduate Diploma in Clinical Pathology from GMC, Trivandrum, and is a Fogarty Fellow graduate in Bioethics from University of Toronto. She worked as a researcher in the Gastroenterology Dept. of GMC, Trivandrum and in the Liver Clinic of Madras Medical College, Chennai. She retired as Deputy Director General, Senior Grade from ICMR, where she was Program Officer for bioethics, traditional medicine research, and earlier for pharmacology, summer studentship for medical undergraduates as well. She was closely involved in the formulation of several ethical guidelines in India under the aegis of ICMR, Dept. of Ayush & NACO.

She is a national & international surveyor for the ethics committee for SIDCER recognition program. She has pioneered Bioethics Education in India and has been instrumental in initiating the first online PG Diploma course in bioethics in India under ICMR-IGNOU joint initiative sponsored by the NIH, USA. She was a member of international panel of 'President Obama's Commission for the Study of Bioethical Issues', Advisory Council of Drug Information Association, India, and other nationally important committees. She was also Dr. TMA Pai Endowment Chair and Adjunct Professor in Bioethics, KMC, Manipal University. She is now a consultant for bioethical issues and traditional medicine research in India and abroad. She has publications in these areas and is also a reviewer for national and international journals for the same. She is a Faculty for Diploma & Masters course in Bioethics and Clinical research. She is the recipient of ISCR Lifetime Achievement Award 2015 and 'Outstanding International Surveyor of Ethics Committees' 2019. She is a senior consultant for Niti Aayog, BIS, G20, WHO, NIH, EU and other agencies, and is recently appointed as Distinguished Scientist Chair by the Ministry of Ayush (traditional Systems of Indian medicine and Homeopathy).



### **Dirk LANZERATH, European Network of Research Ethics Committees (EUREC)**

Dirk Lanzerath is a Professor of Ethics and Research Ethics. He graduated in biology, philosophy and education, and earned his PhD and *venia legendi* (habilitation) from the faculty of philosophy of the University of Bonn. He is now the Secretary General of the European Network of Research Ethics Committees (EUREC), and the managing director of the German Reference Centre for Ethics in the Life Sciences (DRZE), in Bonn (Central Research Institute of the University of Bonn and Research Centre of the Northrhine Westfalian Academy of Sciences, Humanities and the Arts).

He is a member of the board of the Central Ethics Committee at the German Physician Association and of the Ethics Committee of the North-Rhine medical association, of the Ethics Committee of the University of Maastricht, and of the Editorial Board of the Journal "Research Ethics Review".

Dirk Lanzerath is also a study abroad professor for ethics, bioethics, environmental ethics, research integrity, and ethics and the arts, at the Study Abroad Program of the Loyola Marymount University, Los Angeles, Ca. (USA), and at the Academy of International Education (AIB), Bonn.

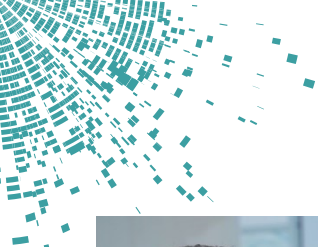


### **Trudo LEMMENS, University of Toronto (Canada)**

Trudo Lemmens (LicJur, LL.M (bioethics), DCL) is Professor and Scholl Chair in Health Law and Policy at the Faculty of Law and the Dalla Lana School of Public Health of the University of Toronto. His research focuses on the interaction between law, governance mechanisms, and ethical norms and values in the context of health care, biomedical research, health product development, and--more generally--knowledge production. His publications include the co-authored book *Medical Law in Canada*, the co-edited volumes *Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability* and *Regulating Creation: Law, Ethics and Policy of Assisted Human Reproduction*, as well as more than 100 chapters and articles in national and international law, policy, science, medicine, and bioethics journals. He has testified before Parliamentary Committees on pharmaceutical policy and euthanasia, and has

been a member of expert committees of, and been consulted by, various organizations such as the World Health Organization, the Pan American Health Organization, the National Academies of Science, and the Council of Canadian Academies. Faculty webpage: <https://www.law.utoronto.ca/faculty-staff/full-time-faculty/trudo-lemmens>





### **Pierre MALLIA, European Group on Ethics & Health Ethics Committee of the Ministry for Health (Malta)**

Pierre Mallia is Professor of Family Medicine and Patients’ Rights at the University of Malta, Medical School where he runs the Bioethics Research Programme and the Medicine and Law Programme. He teaches Bioethics in the Faculties of Medicine, Science, Health Science, Dentistry, Laws, Theology and Engineering. He Chairs the Department of Health Research Ethics Committee, and, the Bioethics Consultative Committee of the Ministry of Health. He was President of the Malta College of Family Doctors for three terms and introduced the international Specialisation of the Royal College of General Practitioners of the UK. He is a member of the Committee for Bioethics of the Council of Europe and is currently a member of the European Group on Ethics in Science and New Technologies.



### **Janet MIFSUD, University of Malta (Malta)**

Prof. Janet Mifsud is presently Head, Department of Clinical Pharmacology and Therapeutics, University of Malta. Her area of expertise is in the pharmacokinetics and pharmacodynamics of drugs used in chronic neurological disorders especially epilepsy, investigating patterns of drug use and misuse, toxicology, bioethical issues and pharmacology education and has published extensively in these areas. She has been involved in pharmacology education of several different health care professionals for over 20 years. The Department co-ordinates over 30 different study-units to over 500 students and two new courses: a BSc in Pharmacology and an MSc in Pharmacotoxicology.

She is presently review Editor for the British Journal of Clinical Pharmacology. Janet has a degree in theology and has been ethics reviewer for proposals to be funded by the European Commission since 2007. She has also been invited to act as member of the external scientific and ethics boards for several projects such as the IMI CARE Corona accelerated R&D in Europe 2020-2025; H2020 Candy Comorbid Analysis of Neurodevelopmental Disorders and Epilepsy 2020 –2025 and IMI2 NeurodeRisk Neurotoxicity De-Risking in Preclinical Drug Discovery 2019-2023.



### **Lorenzo MONTRASIO, Council of Europe**

Lorenzo Montrasio leads the work on equity of access to treatments and technologies at the Council of Europe’s Human Rights Directorate (from 2020). Before joining the Council of Europe, Lorenzo was a regulator serving the European authority network, promoting harmonization and innovation of standards. From 2018 to 2020, he coordinated the European Pharmacopeia (EDQM) cooperation program with hospital blood establishments in 26 countries. From 2011 to 2018, Lorenzo was Head of the Biological Medicines Office at the Italian Medicines Agency (AIFA), coordinating the authorisations of vaccines and biotechnological medicines for the European market. Between 2003 and 2010, as GMP inspector, he contributed to ensuring resilience to medicines’ manufacturing and supply chain. Lorenzo

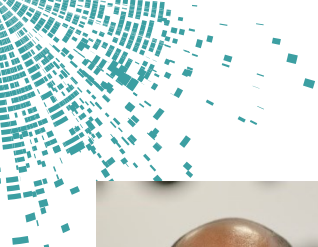
studied Pharmacy (1990-1995), Clinical Pharmacy (1998-2001), and Regulatory Affairs (2001-2005). During his studies, he collaborated with hospitals, universities, and private companies for projects aimed at developing quality in healthcare. Since 2017, he has volunteered with the Saint Luc Hospital at Mvangan (Cameroon).



### **Thérèse MURPHY, European Group on Ethics and New Technologies (EGE) & Queen's University Belfast (UK)**

Thérèse Murphy is Professor of Law at Queen’s University Belfast and Raoul Wallenberg Visiting Professor at Lund University, where she is part of a team working on the future of human rights. Thérèse is a member of the European Group on Ethics in Science and New Technologies, Ireland’s National Research Ethics Committee on Medical Devices, and Northern Ireland’s Clinical Ethics Forum. Previously, she was a member of the UK’s Moral & Ethical Advisory Group coordinated by the Department of Health & Social Care in London. In 2022, working with UNESCO and the Global Campus of Human Rights, she helped to create a MOOC on science and human rights.





### **Shadreck MWALE, University of West London (UK)**

Dr Shadreck Mwale is a Senior Lecturer in Sociology of Health and Illness within the Geller Institute of Ageing and Memory, University of west London. Central to Dr Mwale’s research programme is the goal of reducing health inequalities and improving equity of access and inclusion for diverse populations by examining technological, socio-economic, institutional cultures and practice within health and social care services, in both the UK and global contexts. He is currently leading a large-scale study exploring the use of restraint and restrictive practices in the care of people living with dementia within acute care settings (funded by the National Institute of Health Research). More widely, his programme of research examines the experiences of ethnic minority older people living with dementia in the UK with a focus on the acute hospital setting and social care services. This builds on his programme of work exploring clinical trials and genomic medicine, funded by the Economic and social Research council and Wellcome Trust respectively.



### **Juliet MWANGA, Epicentre Uganda Research Centre (Uganda)**

Juliet Mwanga-Amumpaire is an Associate Professor of Paediatrics and Child Health, and the Director of the Epicentre Research Centre in Uganda. Epicentre is the research entity of Medecins San Frontiers, France. She holds a medical degree from Mbarara University of Science and Technology, a Master of Medicine degree in Paediatrics and Child Health and a PhD in Health Sciences from Makerere University, Kampala. She lectured paediatrics and Child Health at the Mbarara University of Science and Technology in Uganda for over 10 years and later joined Epicentre Research Centre as the research coordinator and later was appointed Director of the research centre. Her research interests are in the areas of infectious diseases and improving child healthcare.

### **Irene NORSTEDT, Director, Directorate D People, DG Research & Innovation (R&I), European Commission**



### **Sandra PETRAGLIA, Agenzia Italiana del Farmaco (AIFA) (Italy)**

Sandra Petraglia is a medical doctor, with a background in Dermatology and Immunology, working at the Italian Medicines Agency (AIFA) since 2004, where she is currently Head of the Pre-Authorisation Department, coordinating the activities related to clinical trials, early access to medicines, support to rare diseases and AIFA funding of independent research. She is also the Italian delegate to the working groups of the EU network on clinical trials and participates in international discussions on these topics as well. Until last year, she has been member of the AIFA COVID19 Task Force and attending the works of several COVID19 working groups at European and international level, focusing mostly on the issues related to clinical trials and early access to medicines.

Previously, she has been working in the Marketing Authorisation Department of AIFA as coordinator of European procedures and clinical assessor, at the Ministry of Health in the medical information sector and as a clinician and PhD fellow in Immunological and Oncological Dermatology.



### **Tatjana POPLAZAROVA, GSK (Belgium)**

Tatjana Poplazarova, MSc Biochemistry, MA-Bioethics, is the Vice President, RD Risk management and Bioethics at GlaxoSmithKline (GSK). Since joining GSK in February 2003, Ms. Poplazarova has led the Scientific and Public Disclosure teams in charge of medical writing, record management, publications, and public disclosure. She is one of the founders of the Clinical transparency team at GSK Biologicals and has been spearheading the application of bioethical decision-making in biopharmaceutical R&D setting. In 2020, she was appointed as head of the GSK Office of the Chief Medical Officer (CMO). Ms. Poplazarova holds an MSc in biochemistry from the University of Zagreb, Croatia, and a joint MA in bioethics from the KU Leuven, Nijmegen, and Padova Universities.



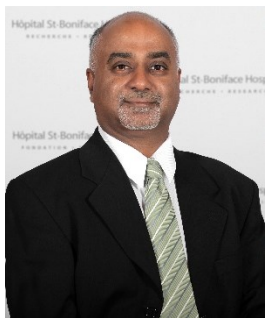




### **Virginie RAGE-ANDRIEU, Conférence Nationale des Comités de Protection des Personnes (CNCP) (France)**

Doctor of Pharmacy and Doctor of Law. I am a lecturer in health law at the University of Montpellier (France), President of the Montpellier Ethics Committee (comité de protection des personnes) and President of the French National Conference of Ethics Committees (Conférence Nationale des Comités de Protection des personnes).

I teach health products and food law to master and pharmacy students. My research focuses on health products, clinical research and ethics.



### **Bram RAMJIWAN, University of Manitoba & St. Boniface Hospital, Winnipeg (Canada)**

Dr. Bram Ramjiawan is the Director of Research Innovation and Regulatory Affairs and Director of Research, Asper Clinical Research Institute at the St. Boniface Hospital and Research Centre in Winnipeg, Canada. He is responsible for the oversight of Clinical Innovation and Research and to ensure that all clinical, regulatory and business issues are handled as required by local, national and international (EMA, FDA, HC) agencies. During his tenure, he has been on teams that have worked on over 200 approved therapeutic products (biologics, drugs, medical devices and foods) globally.

Prior to joining the hospital, Dr. Ramjiawan was with the Government of Canada (National Research Council) as a scientist and as an Industrial Technology advisor who specialized in Life Sciences and biomedical technologies. During this tenure, he has worked on numerous biomedical technologies that have been successfully commercialized and have resulted in the adaption of these technologies in the clinic. He has served on a number of National and International review committees for new medicines and technologies.

He is an expert on clinical trials design, regulations and ethics. He is an adjunct professor of Pharmacology and Therapeutics for the Max Rady College of Medicine, Faculty of Health Sciences at the University of Manitoba. Dr. Ramjiawan is a Fellow of the Canadian Academy of Health Sciences.



### **Raffaella RAVINETTO, Institute of Tropical Medicine, Antwerp & Médecins Sans Frontières (Belgium)**

Raffaella Ravinetto, PharmD, PhD, has a thirty-year experience in commercial and non-commercial clinical research, humanitarian programmes, pharmaceutical policies, and research ethics review.

After an experience as Clinical Research Scientist in the private pharmaceutical sector, she worked as a pharmacist in humanitarian programs in the Balkans and in Africa. In 2002, she joined Médecins Sans Frontières/Doctors Without Borders (MSF), where she held different positions focusing on access to/quality of essential medicines and performed several field assessments in Africa and Latin America.

From 2006 to 2016, she was the head of the Clinical Trials Unit of the Institute of Tropical Medicine (ITM) Antwerp, which supported non-commercial collaborative research programs in sub-Saharan Africa. She is currently a senior researcher and policy advisor at the Public Health Department of the ITM, in charge of a portfolio of research, policy support, education and advocacy in pharmaceutical public health. She is also the chairperson of the ITM Institutional Review Board; the chairperson of the MSF Ethics Review Board; an extraordinary professor at the School of Public Health, University of Western Cape, South Africa; and a senior editor of the BMC Medical Ethics.

### **Alexandra ROLAKI, European Research Council Executive Agency (ERCEA)**




### **Tohlang SEHLOHO, South African Health Products Regulatory Authority (SAHPRA) (South Africa)**

Mr Sehloho is a pharmacist and epidemiologist responsible for various units in the Clinical Evaluations Programme of SAHPRA as Senior Manager. These units include clinical trial protocol evaluations, health products vigilance, clinical safety and efficacy evaluations, proprietary names and API scheduling evaluations, and Section 21 authorisations. He has both technical and management experience in hospital, distribution, retail and, currently, medicines regulation.

He represents SAHPRA on the International Pharmaceutical Regulators Programme (IPRP) Management Committee and in several working groups of the International Coalition of Medicines Regulatory Authorities (ICMRA).





He has published on weight outcomes of human insulin exposure in T1DM, as well as online commentaries on the safety and efficacy of aspirin in cancer. He has also co-authored papers on regulatory situational analysis and strengthening in Africa. He is active on Research Gate as a contributor and is often approached to review manuscripts for various journal publication requests.

### **Esperança SEVENE, Eduardo Mondlane University (Mozambique)**



Dr Esperança Sevene graduated in Medicine and Surgery at the Eduardo Mondlane University (UEM) in 1993, did a master's in Pharmacoepidemiology at the Autonomous University of Barcelona in 2000 and a PhD in Medicine at the University of Barcelona in 2009. She worked on the safe use of medicines and vaccines and was involved in implementing pharmacovigilance in several countries in collaboration with World Health Organization. She was involved in creating the National Bioethics Committee for Health in 2002. Currently, she is an Associate Professor of Clinical Pharmacology, serving as Coordinator of the Doctoral Program in Biosciences and Public Health at UEM, Senior Researcher at the Manhiça Health Research Center and President of the National Bioethics Committee for Health. She also has international

collaborations as a member of the Africa-Europe Foundation Health Strategic Group, Maternal Immunization Working Group and the WHO Advisory Committee on Safety of Medicinal Products, COVID-19 Therapeutics Sub-Committee. Dr Sevene authored over 100 scientific publications in Pharmacoepidemiology and Public Health.

### **Jerome SINGH, South African Medical Research Council (South Africa)**

#### **Nathalie SLOOTMANS, Pfizer (Belgium)**



My name is Nathalie Sloomans. I graduated as an Engineer in Applied Biosciences from the Kempen University College (current Thomas More) in 2010. I am currently working in the Pfizer Clinical Research Unit (Brussels, Belgium) as Clinical Research Regulatory Team Coordinator. The "PCRU" is one of two Pfizer owned Phase 1 units.

I joined the PCRU 5 years ago, to start a new career in the regulatory team. After working for approximately 1 year in this field, I had the opportunity to take over the leadership/coordination of this team. It was the beginning of a great journey for me with implementation of GDPR, CTR pilots and now EU CTR.

Before joining the PCRU I worked at Pfizer Animal Health/Zoetis for 7 years as a Veterinary CRA. This initial role allowed me to gain hands on expertise in clinical research and to touch base on a broad range of responsibilities, including protocol development, monitoring, data verification, building EDC and writing study reports.

During the last five years, I developed expertise in phase 1 monocentric trials. Noteworthy, the PCRU being a Pfizer owned institution, it is active at both sponsor and study site levels, which offers the opportunity to work on all parts of the CTA submission internally. This is giving me great exposure to various aspects the regulatory field of early clinical development.

#### **Dominique SPRUMONT, Council for International Organizations of Medical Sciences (CIOMS)**



Professor of Health Law. Current President of the Research Ethics Committee of Vaud ([www.cer-vd.ch](http://www.cer-vd.ch)). Founding member of the Institute of Health Law (Institut de droit de la santé, IDS) of the University of Neuchâtel (<http://www.unine.ch/ids>) and past vice-director of the Swiss School of Public Health. He collaborated in the drafting of many legislations in the field of health and healthcare at the cantonal, Swiss and European levels. He is also regularly invited by scientific and professional associations in developing their guidelines in those fields, such as the WMA 2008 and 2013 revisions of the Declaration of Helsinki or the 2016 Declaration of Taipei on Health Databases and Biobanks. Expert in the field of public health law with special interest in the regulation of research involving human participants, patient's rights, the regulation of healthcare professionals, pharmaceutical and food stuff regulation, he has written more than 160 scientific publications, articles and book chapters on those issues. He is one of the founders of the European Network of Research Ethics Committees ([www.eurecnet.org](http://www.eurecnet.org)). Since 2006, he is also the coordinator of the initiative Training and Resources in Research Ethics Evaluation (TRREE) (<http://elearning.trree.org>).





### **Nadina STADLER, Independent consultant (Germany)**

Nadina Stadler, PhD, is a capacity building specialist, scientist, and former lead and coordinator of projects within the global health domain, research and regulatory strengthening. Focusing on nurturing networks and advancing partnerships with peer institutions in numerous LMICs, projects she guided facilitated competence development, biomedical investigation and training in quality assurance/strengthening of regulatory systems supporting wider and the appropriate use of quality-assured medicines. She has higher education expertise through previous roles as acting professor and lecturer for clinical research. Nadina’s research interests are clinical and regulatory research, biomarker discovery (NCDs, CDs, AMR), ethics. Drawing on more than 20 years of expertise gained in various countries and within the academic, not-for-profit, non-academic, higher education and regulatory sectors, Nadina focuses on collaborating with international agencies and others towards the development, evaluation and/or implementation of multinational actions in the area of public health/health systems, research and further education.



### **Craig TIPPLE, Drugs for Neglected Diseases initiative (DNDi) (Switzerland)**

Craig is a British physician scientist and drug developer with early phase, clinical pharmacology and late phase experience including regulatory file and approval. He is a qualified specialist in HIV Medicine with a broad knowledge of general medicine and infectious disease. He is currently the R&D Medical Director at the Drugs for Neglected Diseases Initiative, a non-profit R&D organization which develops medicines for neglected infectious diseases and populations. He has responsibility for Translational Medicine, Drug Safety, Regulatory Affairs and Quality and Compliance. He is a former phase 1 clinical unit medical director with qualification in human pharmacology and has a strong interest in patient and public engagement in research.



### **Marta ZAKRZEWSKA, GCPpl Association and PRATIA S.A. (Poland)**

Marta Zakrzewska is a graduate of the Faculty of Management and Marketing in Warsaw. She has been working in clinical research since 2006. In her career so far, she has been involved in research site activities, and in particular responsible for study design, budgeting and contract negotiations.

She is currently the Manager of full-service Phase I unit in Warsaw, focusing on Phase I, bioequivalence, biosimilars and Phase III studies. In her current role, Marta oversees all research conducted at MTZ Clinical Research powered by Pratia.

Since 2016, she has been involved in the GCP PL Association, currently as a member of the Audit Committee. She actively participates in the Research Sites Group, which was established in 2018. This group brings together people involved in clinical research in private and public, inpatient and outpatient clinics, as well as representatives of patients, sponsors and CROs. She has many years of experience as a speaker at professional conferences in the field of clinical research.

## **HEALTHY VOLUNTEERS**

**Rogers ANKUNDA (Uganda)**

**John BURWELL (USA)**

**Kaviya MANOHARAN (India)**

**Muhamad Haziq Bin MOHD MARPHY (Malaysia)**

**Bridget TAREMWA (Uganda)**







## ORGANIZING COMMITTEE : VOLRETHICS COORDINATION GROUP & EC MEMBERS



### **François BOMPART, DNDi (Switzerland) & Inserm Ethics Committee (France)**

François Bompert, MD is the Chair of the Access Committee of the Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation based in Geneva (Switzerland).

His has worked for over 25 years in anti-infective medicines and vaccines, with a focus on emerging and developing countries, mostly within the Sanofi pharmaceutical group. His main fields of interest are related with access to care in resource-limited countries, as well as ethical issues in clinical research. His specific interest in ethical issues related with healthy volunteers started with being a healthy volunteer himself in the 1980s, then an investigator and a sponsor of Phase I studies. He initiated the VolREthics

initiative with the Ethics Committee of the French National Institute for Health and Medical Research (Inserm), then became a member of that committee in 2022. The VolREthics initiative aims at protecting healthy volunteers from exploitation in biomedical research everywhere in the world.

He received his MD from the University of Angers (France) and trained in Clinical Pharmacology at University College London (UK) and Hôpital Cochin in Paris (France).



### **Yamina CHEIKH, Science Policy, Advice and Ethics, DG Research & Innovation, European Commission**

Yamina Cheikh provides administrative and logistic support for the Sector's activities, particularly regarding contribution to ethics-related procedures for expert groups and review of projects (payments and contracts).



### **Hervé CHNEIWEISS, President Inserm Ethics Committee (France)**

Hervé Chneiweiss is a neurologist and neuroscientist, MD-PhD, Research Director at the CNRS. He is currently head of the research centre Neuroscience Paris Seine (CNRS /Inserm/Sorbonne University). Trained as a neurologist (movement disorders, neurogenetics), his scientific work was mainly dedicated to the biology of astrocytes and in the recent period their roles in brain tumour origin, progression and plasticity, identifying new metabolic drivers and therapeutic avenues. He has authored more than 170 academic papers (h 53).

He is also involved in bioethics, presently chair Inserm Ethics Committee (IEC) and past-chair of UNESCO International Bioethics Committee, former member WHO advisory committee on developing global standards for governance and oversight of human genome editing and vice-chair of ARRIGE, expert OECD for recommendation 457 on neurotechnology in health. He wrote several books or chapters on bioethics of human embryos, stem cells, genetics and neuroscience.



### **Lisa DIEPENDAELE, Ethics and Research Integrity Sector, DG Research & Innovation, European Commission**

Lisa Diependaele is a policy officer for the Ethics and Research Integrity Sector of the European Commission. Her work is focused on bioethics and ethics of new and emerging technologies in health research context. In this capacity, Lisa has been involved in the elaboration of policy guidelines, procedures and recommendations for Horizon 2020/Horizon Europe applicants and beneficiaries.

Before joining the Commission in 2020, Lisa was a postdoctoral researcher and assistant academic staff member at Ghent University.





She lectured courses in applied ethics and global ethics as well as social and political philosophy. Her research focussed on ethical issues relating to the protection of pharmaceuticals through patents, data exclusivity and trade secrets, intersections with international investment law, and ethical issues pertaining to the use of algorithms in the context of clinical research and decision-making. Lisa obtained a PhD in Philosophy in 2019, and holds Master’s degrees in International and European Law and Moral Sciences (Ethics).



**François EISINGER, INSERM Ethics Committee (France)**

Francois Eisinger, MD (Internal Medicine), PhD Public Health (Associate Professor). He is current member of the National Advisory Committee for Public Health (on the behalf of French Health Ministry) in which he is Chair of “Health determinants and non-transmissible diseases” commission. He is also member of the Ethical committee of the INSERM since 2002. Chair of two working groups: one about management of incidentals findings and one about ethical issues related to patients enrollment in clinical trials. He is Editorial Consultant for the International Journal for Equity in Health, a member of the French association of health economist and a member of the Society for Risk analysis



**François HIRSCH, Inserm Ethics Committee (France)**

François Hirsch graduated in immunology from the Pasteur Institute and in Science & Medical Ethics from Paris-Sud University. He spent 30 years at the National Institute for Health and Medical Research (Inserm) holding various positions in scientific research and research administration, including Secretary General of the Ethics Committee and Deputy Director of the Health Technologies Institute. For three years, he was a National Expert seconded to the Governance and Ethics Unit of the European Commission (EC), where he contributed to the organization of the ethical evaluation of the research projects submitted for funding. François Hirsch is currently a member of the Inserm Ethics Committee, Secretary of the Ile-de-France 7 Committee for the Protection of Persons (national registered IRB) and a member of the Board of Directors of the National Conference of CPPs. At the international level, he holds responsibilities as Secretary General of the International Association for Responsible Research In Genome Editing (ARRIGE) and leads the international initiative VolREthics aiming at establishing good practices for research involving healthy volunteers. He is also an ethics evaluator for various European Commission agencies and a member of the European network of research ethics committees (EURECNet).



**Meriem KARKAR-GEOFFROY, Intern, Inserm Ethics Committee (France)**

After obtaining a law degree (University of Paris Descartes), Meriem Karkar-Geoffroy specialized in health and bioethics law for her master’s degree (University of Paris-Est-Créteil). She is now preparing a second master's degree in ethics of scientific research (University of Paris-Saclay, Espace éthique Ile-de-France) parallel to an internship at the Inserm ethics committee focusing on the VolREthics initiative.

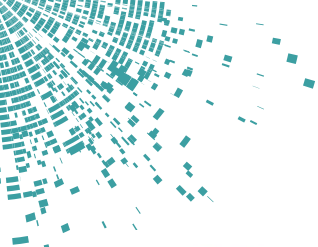


**Christine LEMAITRE, Inserm Ethics Committee (France)**

Christine Lemaître joined Inserm in 2007 after a career as quality and R&D manager in the food-processing industry. She currently acts as General Secretary of the Inserm Ethics Committee, and carries out scientific and research support missions at the "Cell Biology, Development and Evolution" thematic institute within Inserm and Aviesan, the French National Alliance for Life Sciences and Health, aiming to coordinate and lead French research in these fields. She worked at the "Genetics, Genomics and Bioinformatics" Institute until 2018. At the international level, she is member of the board of the International Association for Responsible Research and Innovation in Genome Editing (ARRIGE), of which she is one of the founders. Christine Lemaître is an Inserm research engineer; she is a graduate of the National High School of Engineering in Agronomy and Food Industries of Nancy.

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### **Flavie MATHIEU, Inserm Ethics Committee (France)**

Flavie Mathieu has a strong experience in genetic epidemiology in both methodological development and data analysis of complex diseases. Between 2001 and 2018, she managed several research projects focusing on genetics and gene-environment interaction on cardiovascular and psychiatric diseases and then on type 1 diabetes.

Since 2003, she teaches biostatistics, genetics of complex diseases and genetic epidemiology and manages master degree, MD and PhD students at the University of Paris, at the Faculty of Medecine of Créteil, the “Conservatoire des arts et métiers” and the Efrei Paris engineering school of digital technologies.

Since 2016, she joins the team “Sciences and society of Inserm”, where she heads the “Collège des relecteurs de l’Inserm” and she develops participative research and patient’s empowerment. She is also a member of the Inserm ethics committee, the think tank network with patient organizations of Inserm and heads the think tank “Information and consents for all, even for vulnerable populations” as part of the “Collège des relecteurs”.



### **Isabelle REMY-JOUET, Inserm Ethics Committee (France)**

After a PhD in biology, Isabelle Remy-Jouet is interested in the detection of radicals’ species in health. She is also actively involved in continuous improvement within the quality management system of research in Inserm (ISO9001) and a significant part of its activity concerns the objectives of sustainable development and the ecological transition in research.

In the field of research on free radicals and pathologies, she has contributed to several clinical studies. Holder of a master's degree in ethics, health and social sciences, she has worked in the Inserm Ethics Committee since 2016 and is particularly interested in contexts leading to inequity and vulnerability. Here is one of her relevant publications: From informed consent to negotiated consent: an approach of research among unevenly developed countries? ethics committee of Inserm, 2018.

### **Yamina SADANI, Inserm Ethics Committee (France)**

After studying Pharmacy, I worked as a Major Account Consultant in the French subsidiary of an American group specialized in corporate rating. Then, I integrated a CRO in which I was in charge of clinical trial reports writing.

I joined Inserm in 2009 as Assistant to the Directorate-General and two Thematic Institutes (Cancer and Genetics), then to the National and Foreign Affairs department. I am graduated with a Master’s degree in Sociology and in History.

I currently hold the position of Executive Assistant in the department of Scientific information and Communication where I am contributing to the activities of the Institutional Relations Service, the Ethics Committee and the History Committee.

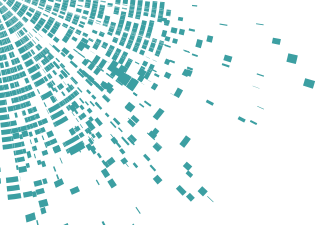


### **Corinne SEBASTIANI, Inserm Ethics Committee (France)**

Corinne Sébastiani is a Molecular Biologist by degree focused in Genomic (sequencing and cartography), with an MSc in intellectual property and patent law and with extensive experience in clinical research focused on new technologies (cellular therapy, gene therapy, vaccine...). Her main research interests include the animation and the steering of the French community on new health technologies. She is a member of steering committee of Research Group on organoids of National Centre for Scientific Research (CNRS) including work packages of clinical research and regulation, bioethics and training. She is also a member of the Inserm Ethics Committee.







## Edyta SIKORSKA, Ethics and Research Integrity Sector, DG Research & Innovation, European Commission

Edyta SIKORSKA, a clinical psychologist by background, a specialist in Solution-Focused Brief Therapy (SFBT). For several years, she worked as psychologist-counsellor for NGOs and local government in Gdansk, Poland.

As from 2009 she has been working for the EU Institutions. Prior to her current position, she was responsible for public procurement in the Science in Society Unit.

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