


Sponsors

ESPACE ÉTHIQUE
RÉGION ILE-DE-FRANCE

 **IReSP**
Institut pour la Recherche
en Santé Publique

THE CONVERSATION


Organisation
des Nations Unies
pour l'éducation,
la science et la culture

• sous le patronage
de la Commission
nationale française
pour l'UNESCO



DNDi
Drugs for Neglected Diseases *initiative*

anrs
MALADIES INFECTIEUSES
ÉMERGENTES **Inserm**




EDCTP

DAY 1 – SETTING THE SCENE

February 15th, 2022

▶ 10H00 – 10H45 • Welcoming remarks

Hervé Chneiweiss

President, Inserm Ethics Committee

François Hirsch

Inserm Ethics Committee

Irakli Khodeli

UNESCO, Bioethics and Ethics of Science and Technology Section

▶ 10H45 – 12H30 • Roundtable 1

Clinical studies with administration of pharmaceutical compounds

Moderator François Bompard, *DNDi*

Speakers **Regulatory agencies:** Pierre Demolis, *Agence Nationale de Sécurité du Médicament et des produits de santé (France)/ European Medicines Agency*
Pharmaceutical companies: Mukesh Kumar, *Cipla (India)* & Aude Le Roux, *Sanofi (France)*
Contract Research Organisations: Deepa Arora, *Clinixel (India)* & Nicolas Fauchoux, *Biotrial (France/USA)*
Q & A

▶ 12H30 – 13H30 • LUNCH BREAK

▶ 13H30 – 14H50 • Roundtable 1 (continued)

**Clinical studies with administration of pharmaceutical compounds:
Key ethical issues**

Moderator Pierre Mallia, *Health Ethics Committee of the Ministry for Health (Malta)*

Speakers Shadreck Mwale, *University of West London (UK)*
Jill A Fisher, *University of North Carolina (USA)*
Nandini Kumar, *FERCI (India)*
Wei Zhu, *Shanghai Ethics Committee for Clinical Research (P. R. China)*
Q&A

▶ 14H50 – 15H50 • Roundtable 2

Studies in vulnerable populations

Moderator Tumani Corrah, *Africa Research Excellence Fund (Gambia)*

Speakers Emmanuel Baron, *Epicentre/MSF*
Mukandu Basua Babintu Leyka, *Institut supérieur des techniques médicales, Kinshasa (Democratic Republic of Congo)*
Samuel Verges, *Université Grenoble Alpes (France)*
Q&A

▶ 15H50 – 16H05 • BREAK

▶ **16H05 – 17H05 • Roundtable 3**

Human infection challenge studies

Moderator Lionel Cavicchioli, *The Conversation (France)*

Speakers Katherine Littler, *WHO*
Odile Launay, *Inserm, AP-HP (France)*
Jonathan Pugh, *University of Oxford (UK)*
Ingrid Callies, *CCNE (France)*
Q&A

▶ **17h05 – 17h35 • Further steps**

Moderator Mylène Botbol-Baum, *Inserm Ethics Committee*

Speaker François Eisinger, *Inserm Ethics Committee*

Open discussion with all participants

DAY 2 – DRAFTING RECOMMENDATIONS

February 16th, 2022

▶ 11H00 – 12H00 • Roundtable 4

Ethical issues raised by non-clinical research involving healthy persons

Moderator Dirk Lanzerath, *European Network of Research Ethics Committees (EUREC)*

Speakers Caroline Ollivier-Yaniv, *Université Paris-Est Créteil (France)*
Karim Ndiaye, *ICM (France)*
Marie-Noëlle Ungeheuer, *Institut Pasteur (France)*
Q&A

▶ 12H00 – 13H00 • Roundtable 5

Non-drug related clinical studies: vaccines, living cells donation, medical devices

Moderator Hélène Espérou, *Inserm (France)*

Speakers Wali Diouf, *Anrs-MIE (Guinea)*
Antony Fuhr, *Fraunhofer, (Germany)*
Thierry Chevalier, *Inserm (France)*
Q&A

▶ 13H00 – 14H00 • LUNCH BREAK

▶ 14H00 – 15H40 • Roundtable 6

Regulations to protect healthy volunteers Key features and lessons learned

Moderator Christiane Druml, *Austrian Bioethics Commission & Medical University, Vienna (Austria)*

Speakers François Eisinger, *Institut Paoli-Calmettes (France)*, to present the National Registry of Volunteers for Biomedical Research (Data from General Directorate of Health/French Health Ministry)
Henri Caplain, *Association Française de Pharmacologie Translationnelle (AFPT) (France)*
Chun Keat Chew, *Institute for Clinical Research (Malaysia)*
Malcolm Boyce, *Hammersmith Medicines Research (UK)*
Nandini Kumar, *FERCI (India)*
My Elhassan Elkarimi *Anti-Poison & Pharmacovigilance Center (Morocco)*
Q&A

▶ 15H40 – 15H55 • BREAK

► 15H55 – 17H15 • Towards Good Practices

Aiming for 4Rs: Respect, Reduce, Refine and Replace healthy volunteers

Moderators Paul-Loup Weil-Dubuc & Vincent Israel-Jost, *EERIdF, Univ. Paris Saclay, (France)*

Speakers **Healthy Volunteers as Model Organisms: Borrowing from Animal Research Ethics to Improve Human Trials:** Jill A. Fisher *University of North Carolina (USA)*

Respect: David B. Resnik, *NIEHS (USA)*

Reduce: Pierre Demolis, *Agence Nationale de Sécurité du Médicament et des produits de santé (France)/ European Medicines Agency*

Refine and replace: Marylore Chenel, *Pharmetheus, (Sweden)*

Perspectives for future guidelines: Lembit Rägo, *CIOMS*

Q&A

► 17H15 – 17H45 • Keynote Lecture

Introduced by **Hervé Chneiweiss**, *President of the Inserm Ethics Committee*

Ezechiël Emanuel

Vice Provost for Global Initiatives, Co-Director, Healthcare Transformation Institute, University of Pennsylvania (USA)