



VoREthics third plenary meeting

Towards the dissemination of the “Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials”

April 18th-19th 2024

In partnership with the French National Academy of Medicine, Paris, France



Day 1, Thursday April 18, 2024 – 10:00 to 18:30 CET

Welcome Addresses

10:00 to 10:40
40 min

Chairperson: **Lionel Cavicchioli**, *The Conversation*

- **Catherine Barthélémy**, President National Academy of Medicine
- **Didier Samuel**, CEO, the Institut national de la santé et de la recherche médicale (INSERM)
- **Hervé Chneiweiss**, Chair, INSERM Ethics Committee

10:40 to 10:45
5 min

Meeting Objectives, **François Hirsch**, INSERM Ethics Committee

VoREthics’ Working Groups Reports

10:45 to 11:05
20 min

Chairperson: **François Bompard**, INSERM Ethics Committee
Presentation of the 3 Working Groups Key topics.

- Protect from risk of exploitation: **Sucheta B Kurundkar** (Dept of Biotechnology, Ministry of Science & Technology, India) & **Yves Donazzolo** (Eurofins Optimed, France)

11:05 to 11:25
20 min

- Protect from risk of harm: **Jill Fisher** (University of North Carolina, USA) & **Shadreck Mwale** (University of West London, UK)

11:25 to 11:45
20 min

- Ensure validity of studies and promote 4Rs (Respect, Refine, Reduce, Replace Healthy Volunteers): **CK Chew** (Institute for Clinical Research, Malaysia)

11:45 to 12:15
30 min

General Discussion: How to value and consolidate the WGs outputs?

Lunch break – 12:15 to 13:45

The “Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials”

13:45 to 14:35
50 min

Jill Fisher (University of North Carolina, USA) & **François Bompert** (INSERM Ethics Committee)

14:35 to 14:45
10 min

General Discussion: Q&A

Industry, Contract Research Organizations and Researchers Round Table

14:45 to 16:00
75 min

Chairpersons: **Yves Donazzolo** (Eurofins Optimed, France) & **Luc Bigel** (DLA Piper, France)

- **Aude Le-Roux** (Sanofi, France)
- **Deepa Arora** (Clinexel, India)
- **Hélène Espérou** (INSERM, France)
- **Udo Schuklenk** (Editor-in-Chief at Bioethics)

16:00 to 16:15
15 min

General Discussion: Q&A

Coffee break – 16:15 to 16:45

European Round Table Discussion

16:45 to 18:00
75 min

Chairpersons: **Shereen Cox**, (University of Oslo, Norway) & **Nadina Stadler** (Independent consultant, Germany)

- **Simon Kolstoe** (University of Portsmouth, UK)
- **Lisa Diependaele** (European Commission)
- **Dirk Lanzerath** (EUREC, Germany)
- **Vania Wisdom** (The Lancet)

Open Discussion

18:00 to 18:30
30 min

Chairpersons: **Henri Caplain** (AFPT - Le Club Phase I, France), **Achille Massougbdji** (Institut de Recherche Clinique, Bénin & I.R.D., France)

Adjourn Day 1

Day 2, Friday April 19, 2024 – 9:30 to 17:30 CET

International Round Table Discussion

9:30 to 11:00

90 min

Chairpersons: **Dafna Feinholtz** (UNESCO) & **Maya Peled Raz** (University of Haifa, Israel)

- **Carleigh Krubiner** (Wellcome Trust, UK)
- **Nicholas Leow Chun Wei** (NPRA, Malaysia)
- **Christopher Ddamulira** (UNCST, Uganda)
- **Craig Tipple** (DNDi, Switzerland)
- **Dominique Sprumont** (CIOMS)

11:00 to 11:15

15 min

General Discussion: Q&A

Coffee break – 11:15 to 11:30

Dissemination of the Ethics Charter: Breakout Sessions

11:30 to 13:00

90 min

Breakout Sessions' Setting, **Flavie Mathieu**, INSERM (France)

- *Breakout session 1: How to best implement the Charter? What obstacles to anticipate? What synergies?*

Chairpersons: **Virginie Rage-Andrieu**, CNCP (France) & **Roberto Abadie**, University of Nebraska-Lincoln (USA)

- *Breakout session 2: What are the partners to be involved in its implementation?*

Chairpersons: **Anne-Marie Taburet**, CPPIdf7 (France) & **Janaka Pushpakumara**, University of Rajaratay (Sri Lanka)

- *Breakout session 3: How to best involve healthy volunteers and civil society?*

Chairpersons: **Flavie Mathieu**, INSERM (France) & **Bram Ramjiawan**, University of Manitoba & St. Boniface Hospital, Winnipeg (Canada)

- *Breakout session 4: Do we identify priority countries/regions for implementation?*

Chairpersons: **Shereen Cox**, University of Oslo (Norway) & **François Eisinger**, INSERM Ethics Committee (France)

Lunch break – 13:00 to 14:00

Dissemination of the Ethics Charter: Reports from the Breakout Sessions

14:00 to 15:00
60 min

Chairpersons: **Agnès Saint Raymond** (Former EMA Head of International Affairs Division, France) & **Fabrizio De Ponti** (Università di Bologna, Italia)

What is next for VoREthics: Gaining from Other Initiatives, from Associations

15:00 to 16:15
75 min

Chairpersons: **Silvia Garcia Perez** (EDCTP3) & **Lisa Diependaele** (European Commission)

- ✓ PREPARED initiative: **Doris Schroeder** (University of Central Lancashire, UK&Cyprus)
- ✓ AccessAfrica2 initiative: **Vivian Nchanchou Mbanj** (University of Oslo, Norway)
- ✓ Seintinelles: **Guillemette Jacob** (France)
- ✓ ICAREB-Clin: **Hélène Laude** (Institut Pasteur, France)

What is next for VoREthics: Gaining from Healthy Volunteers Experience

16:15 to 17:00
45 min

Chairperson: **Shadreck Mwale** (University of West London, UK)

- Jamie Norward (USA)
- Manoharan Kaviya (India)
- Badrishah Izwan (Malaysia)
- Martin Enserink (Deputy News Editor at *Science* magazine, The Netherlands)

Concluding Remarks

17:00 to 17:30
30 min

François Hirsch, INSERM Ethics Committee
François Bompard, INSERM Ethics Committee & DNDi

Adjourn Day 2

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