



# VoREthics third plenary meeting

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

April 18<sup>th</sup>-19<sup>th</sup> 2024

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



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

#### Welcome Adresses

**10:00 to 10:40**  
40 min

Chairperson: **Lionel Cavicchioli**, Health Section Editor at The Conversation France

- **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

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

**10:45 to 11:05**  
20 min

- 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)
- **Aneta Sitarska-Haber** (GCPpl Association, Poland)
- **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** (Senior Executive Editor at 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: **Corinne Sebastiani**, INSERM Ethics Committee (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 VolREthics: 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 Mbanya** (University of Oslo, Norway)
- ✓ Seintinelles: **Guillemette Jacob** (France)
- ✓ ICAREB-Clin: **Hélène Laude** (Institut Pasteur, France)

## What is next for VolREthics: Gaining from Healthy Volunteers Experience

16:15 to 17:00  
45 min

Chairperson: **François Bompert**, INSERM Ethics Committee

- ✓ Françoise Albinet (France)
- ✓ Jamie Noward (USA)
- ✓ Kaviya Manoharan (India)
- ✓ Badrishah Izwan (Malaysia)
- ✓ Martin Enserink (Deputy News Editor at Science, The Netherlands)

## Concluding Remarks

17:00 to 17:30  
30 min

Next Steps, **François Hirsch** (INSERM Ethics Committee)

**Elisabeth Elefant**, Ethics Committee, National Academy of Medicine (France)  
**Hervé Chneiweiss**, Chair, INSERM Ethics Committee

## Adjourn Day 2

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