VolREthics 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
Chairperson: Lionel Cavicchioli, The Conversation
40 min
- Catherine Barthélemy, 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
Meeting Objectives, François Hirsch, INSERM Ethics Committee
5 min

VolREthics’ Working Groups Reports

Chairperson: François Bompart, 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”

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<th>Event</th>
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<tr>
<td>13:45 to 14:35</td>
<td>Jill Fisher (University of North Carolina, USA) &amp; François Bompart (INSERM Ethics Committee)</td>
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<tr>
<td>14:35 to 14:45</td>
<td>General Discussion: Q&amp;A</td>
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<td>14:45 to 16:00</td>
<td>Industry, Contract Research Organizations and Researchers Round Table</td>
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<tr>
<td>16:00 to 16:15</td>
<td>General Discussion: Q&amp;A</td>
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### Coffee break – 16:15 to 16:45

### European Round Table Discussion

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<tr>
<td>16:45 to 18:00</td>
<td>Chairpersons: Shereen Cox, (University of Oslo, Norway) &amp; Nadina Stadler (Independent consultant, Germany)</td>
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<td>• Simon Kolstoe (University of Portsmouth, UK)</td>
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<td>• Lisa Diependaele (European Commission)</td>
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<td>• Dirk Lanzerath (EUREC, Germany)</td>
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<td>• Vania Wisdom (The Lancet)</td>
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### Open Discussion

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<td>18:00 to 18:30</td>
<td>Chairpersons: Henri Caplain (AFPT - Le Club Phase I, France), Achille Massougbdj (Institut de Recherche Clinique, Bénin &amp; I.R.D., France)</td>
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### Adjourn Day 1
# Day 2, Friday April 19, 2024 – 9:30 to 17:30 CET

## International Round Table Discussion

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<th>Time</th>
<th>Session</th>
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<td>9:30 to 11:00</td>
<td><strong>Chairpersons:</strong> Dafna Feinholtz (UNESCO) &amp; Maya Peled Raz (University of Haifa, Israel)</td>
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<tr>
<td>11:00 to 11:15</td>
<td><strong>General Discussion:</strong> Q&amp;A</td>
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<td>11:30 to 13:00</td>
<td><strong>Dissemination of the Ethics Charter:</strong> Breakout Sessions</td>
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<td>13:00 to 14:00</td>
<td><strong>Lunch break</strong></td>
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### 9:30 to 11:00

- **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

- **General Discussion:** Q&A

### 11:30 to 13:00

**Dissemination of the Ethics Charter:** Breakout Sessions

- **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**

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**

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

- PREPARED initiative: **Doris Schroeder** (University of Central Lancashire, UK & Cyprus)
- AccessAfrica2 initiative: **Vivian Nchanchou Mbany** (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**

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**

**François Hirsch**, INSERM Ethics Committee
**François Bompart**, INSERM Ethics Committee & DNDi

### Adjourn Day 2

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