# Second plenary meeting of the
**Volunteers in Research and Ethics (VoREthics) Initiative**

#### 24-25 April 2023

Covent Garden (COVE) building, Place Rogier 16, 1210 Brussels

A2 – Auditorium 4-15 (4th floor)

## DAY 1 – 24 April 2023 – 09:30 to 17:30 CET

### Welcome Addresses

<table>
<thead>
<tr>
<th>Time</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>09:30</td>
<td>Hervé CHNEIWEISS, Chair of the Institut National de la Santé et de la Recherche Médicale (INSERM) Ethics Committee (France)</td>
<td>10 min</td>
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<td>09:40</td>
<td>Irene NORSTEDT, Director, Directorate D People, DG Research &amp; Innovation (R&amp;I), European Commission</td>
<td>10 min</td>
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<td>09:50</td>
<td>François HIRSCH, INSERM Ethics Committee (France)</td>
<td>10 min</td>
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### SESSION 1 – Healthy volunteers’ involvement in research projects

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<tr>
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<tbody>
<tr>
<td>10:00</td>
<td><em>Introduction by the Chairs</em></td>
<td>Maria-Filipa FERRAZ-DE-OLIVEIRA, European Research Council Executive Agency (ERC) &amp; Dirk LANZERATH, European Network of Research Ethics Committees (EUREC)</td>
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<tr>
<td>10:05</td>
<td><em>Healthy volunteers in interventional biomedical research</em></td>
<td>Ingrid KLIN, EUFEMED and European Forum for Good Clinical Practice (EFGCP)</td>
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<td>10:20</td>
<td><em>Healthy volunteers in human and social sciences research</em></td>
<td>Juliet MWANGA, Epicentre Uganda Research Centre (Uganda)</td>
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<td>10:35</td>
<td><em>Healthy volunteers and decentralised clinical trials: examples and points to consider</em></td>
<td>Pierre-Henri BERTOYE, MOH CNRIPH (France)</td>
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<td>11:00</td>
<td><em>Q&amp;A</em></td>
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### Coffee Break

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<tr>
<td>11:00</td>
<td><em>Coffee Break</em></td>
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SESSION 2 – VoIREthics progress to date

11:20 – 11:25  
Introduction by the Chairs
5 min

Montserrat BLAZQUEZ-DOMINGO, European and Developing Countries Clinical Trials Partnership, EDCTP2 Programme & Virginie RAGE-ANDRIEU, Conférence Nationale des Comités de Protection des Personnes (CNCP) (France)

11:25 – 11:55  
Healthy volunteers testimonies
30 min

- Rogers ANKUNDA (Uganda)
- John BURWELL (USA)
- Kaviya MANOHARAN (India)
- Muhamad Haziq Bin MOHD MARPHY (Malaysia)
- Bridget TAREMWA (Uganda)

11:55 – 12:05  
Report of the first plenary meeting
10 min

François BOMPART, Drugs for Neglected Diseases Initiative (DNDi) (Switzerland) & INSERM Ethics Committee (France)

12:05 – 12:55  
Reports of the regional meetings
50 min

- Elisabeth ALLEN, University of Cape Town & TGHN (South Africa) & Esperança SEVENE, Eduardo Mondlane University (Mozambique): Report of the Africa meeting
- Nandini KUMAR, Forum for Ethics Review Committees (India) & Chun Keat CHEW, Institute for Clinical Research (Malaysia): Report of the Asia meeting
- Jill FISHER, University of North Carolina (USA): Report of the North America meeting
- Danilo Cesar GALINDO BEDOR, Federal University of Pernambuco (Brazil): Report of the Latin America meeting
- Lisa DIEPENDAELE, Ethics and Research Integrity Sector, DG Research & Innovation, European Commission & Alexandra ROLAKI, European Research Council Executive Agency (ERCEA): Report of the Europe meeting

SESSION 3 – Breakout sessions to discuss good practices

12:55 – 13:05  
Introduction to the parallel breakout sessions
10 min

François BOMPART, Drugs for Neglected Diseases Initiative (DNDi) (Switzerland) & INSERM Ethics Committee (France)

13:05 – 14:30  
Working lunch and continued discussion
1h25 min
Breakout session 1: Protection from exploitation (1)

Chairpersons: Hélène ESPEROU, INSERM (France) & Shadreck MWALE, University of West London (UK)

Focus on:
- Informed consent processes and documents tailored to volunteers’ needs and vulnerabilities
- Processes to determine fair amounts of compensation
- Management of study completion bonuses vs. right to withdraw

Breakout session 2: Protection from exploitation (2)

Chairpersons: Roberto ABADIE, University of Nebraska-Lincoln (USA) & Nadina STADLER, Independent consultant (Germany)

Focus on:
- Permitted means of recruitment of healthy volunteers
- Standards to ensure well-being during the study
- Information of healthy volunteers on study findings

Breakout session 3: Protection from harm and ensuring validity of studies (1)

Chairpersons: Janet MIFSUD, University of Malta (Malta) & Bram RAMJIAWAN, University of Manitoba & St. Boniface Hospital, Winnipeg (Canada)

Focus on:
- Adapted Institutional Review Boards and study review processes
- Accreditation and inspection of investigators and investigational sites
- Representativity of healthy volunteers for target populations

Breakout session 4: Protection from harm and ensuring validity of studies (2)

Chairpersons: Lorenzo MONTRASIO, Council of Europe & Craig TIPPLE, Drugs for Neglected Diseases Initiative (Switzerland)

Focus on:
- Healthy volunteers’ registries
- Management of incidental findings
- Insurance coverage for adverse events occurring during and after the study (topic introduced by Luc BIGEL, DLA Piper France LLP)

Coffee break & Consolidation of breakout sessions recommendations

SESSION 4 – Keynote Lecture

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

Introduced by Elisabeth ALLEN, University of Cape Town & TGHN Africa (South Africa)

Q&A and discussion
**DAY 2 – 25 April 2023 – 09:00 to 18:00 CET**

### SESSION 5 – Reporting of breakout sessions

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Duration</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Welcome &amp; introduction by the Chairs</td>
<td>10 min</td>
<td>Jill FISHER, University of North Carolina (USA) &amp; James A HOUGHTON, National University of Ireland, Galway (Ireland)</td>
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<td>09:10</td>
<td>Reports of the breakout-sessions</td>
<td>1h30 min</td>
<td>1. Protection from exploitation (45 minutes, including Q&amp;A)</td>
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<td>2. Protection from harm and ensuring validity of studies (45 minutes, including Q&amp;A)</td>
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<td>10:40</td>
<td>Coffee break</td>
<td>20 min</td>
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### SESSION 6 - Roundtable discussions

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<tr>
<th>Time</th>
<th>Roundtable 1: Relevance of proposals made for non-pharmaceutical biomedical research areas</th>
<th>Duration</th>
<th>Details</th>
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<tr>
<td>11:00</td>
<td>Roundtable 1: Relevance of proposals made for non-pharmaceutical biomedical research areas</td>
<td>60 min</td>
<td>Chairpersons: Fabrice GZIL, Espace Éthique Ile-de-France (France) &amp; Esperança SEVENE, Eduardo Mondlane University (Mozambique) Panellists:</td>
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<td>- Thomas HINAULT, INSERM (France): Social sciences</td>
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<td>- Simon KOLSTOE, University of Portsmouth (UK): Controlled Human Infection Models</td>
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<td>- Thérèse MURPHY, European Group on Ethics and New Technologies (EGE) &amp; Queen's University Belfast (UK): Medical Devices</td>
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<td>- Juliet MWANGA, Epicentre Uganda Research Centre (Uganda): Epidemiology</td>
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<td>- Raffaella RAVINETTO, Institute of Tropical Medicine, Antwerp &amp; Médecins Sans Frontières (Belgium): IRB Chair</td>
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<tr>
<td>12:00</td>
<td>Roundtable 2: Study sponsors and CROs</td>
<td>60 min</td>
<td>Chairpersons: Ignasi BELDA, EIT Health ELSI Board (Spain) &amp; Henri CAPLAIN, Association Française de Pharmacologie Translationnelle (AFPT) (France) Panellists:</td>
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<td>- Deepa ARORA, CLINEXEL (India)</td>
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<td>- Pierre-Henri BERTOYE, UNICANCER (France)</td>
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<td>- Yves DONAZZOLO, European Federation for Exploratory Medicines Development (EUFEMED) and the European CRO Federation (EUCROF)</td>
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<td>- Tatjana POPLAZAROVA, GSK (Belgium)</td>
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<td>- Nathalie SLOOTMANS, Pfizer (Belgium)</td>
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<td>- Marta ZAKRZEWSKA, GCPpl Association and PRATIA S.A. (Poland)</td>
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13:00 – 13:50  |  Lunch  
50 min

13:50 – 15:00  |  Roundtable 3: Regulatory agencies  
70 min
Chairpersons: Pierre DEMOLIS, Agence Nationale de Sécurité du Médicament et des produits de santé (France) & Trudo LEMMENS, University of Toronto (Canada)
Panellists:
- Maria-Antonietta ANTONELLI, European Medicines Agency (EMA)
- Calvin BERTRAND, Direction Générale de la Santé (France)
- Natalie KLEIN, Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (USA)
- Nicholas C.W LEOW, National Pharmaceutical Regulatory Agency (NPRA) (Malaysia)
- Sandra PETRAGLIA, Agenzia Italiana del Farmaco (AIFA) (Italy)
- Tohlang SEHLOHO, South African Health Products Regulatory Authority (SAHPRA) (South Africa)

15:00 – 15:15  |  Coffee break  
15 min

SESSION 7 – Open discussion

15:15 – 16:00  |  Open discussion, including topics for further work  
45 min
Discussion moderated by:
- Irakli KHODELI, UNESCO
- Carleigh KRUBINER, Wellcome Trust (UK)
- Pierre MALLIA, European Group on Ethics and New Technologies (EGE) & Health Ethics Committee of the Ministry for Health (Malta)

SESSION 8 – Conclusions & Next steps

16:00 – 16:30  |  Next steps: How to progress in the elaboration of international guidelines for the protection of healthy volunteers globally?  
30 min
- Irakli KHODELI, UNESCO
- Dominique SPRUMONT, Council for International Organizations of Medical Sciences (CIOMS)

16:30 – 17:00  |  Concluding remarks  
15 min
- Joanna DRAKE, Deputy Director-General, DG Research & Innovation, European Commission
- Hervé CHNEIWEISS, INSERM Ethics Committee (France)

End of day 2
MEETING SPONSORS

Co-funded by the European Union