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>Name</th>
<th>Position</th>
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<tr>
<td>09:30 – 09:40</td>
<td>Hervé CHNEIWEISS</td>
<td>Chair of the Institut national de la santé et de la recherche médicale (INSERM) Ethics Committee (France)</td>
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<td>09:40 – 09:50</td>
<td>Irene NORSTEDT</td>
<td>Director, Directorate D People, DG Research &amp; Innovation (R&amp;I), European Commission</td>
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<td>09:50 – 10:00</td>
<td>François HIRSCHE</td>
<td>INSERM Ethics Committee (France)</td>
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SESSION 1 – Healthy volunteers’ involvement in research projects

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<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
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<tr>
<td>10:00 – 10:05</td>
<td>Introduction by the Chairs</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 – 10:20</td>
<td>Healthy volunteers in interventional biomedical research</td>
<td>Ingrid KLINNANN, EUFEMED and European Forum for Good Clinical Practice (EFGCP)</td>
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<td>10:20 – 10:35</td>
<td>Healthy volunteers in human and social sciences research</td>
<td>Juliet MWANGA, Epicentre Uganda Research Centre (Uganda)</td>
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<td>10:35 – 10:50</td>
<td>Healthy volunteers and decentralised clinical trials: examples and points to consider</td>
<td>Pierre-Henri BERTOYE, MOH CNRIPH (France)</td>
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<td>10:50 – 11:00</td>
<td>Q&amp;A</td>
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<td>11:00 – 11:20</td>
<td>Coffee Break</td>
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SESSION 2 – VoREthics progress to date

11:20 – 11:25  Introduction by the Chairs
5 min
Montserrat BLASQUEZ-DOMINIGO, 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 EISINGER, INSERM Ethics Committee (France)

13:05 – 14:30  Group photo, working lunch and continued discussion
1h25 min
14:30 – 16:00

**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)

16:00 – 16:30

Coffee break & Consolidation of breakout sessions recommendations

30 min

SESSION 4 – Keynote Lecture

16:30 – 17:00

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

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

17:00 – 17:30

Q&A and discussion

30 min
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<th>Duration</th>
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<tr>
<td>09:00 – 09:10</td>
<td><strong>Welcome &amp; Introduction by the Chairs</strong>&lt;br&gt;<strong>Jill FISHER</strong>, University of North Carolina (USA) &amp; <strong>James A HOUGHTON</strong>, National University of Ireland, Galway (Ireland)</td>
<td>10 min</td>
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<td>09:10 – 10:40</td>
<td><strong>Reports of the breakout-sessions</strong>&lt;br&gt;1. Protection from exploitation (45 minutes, including Q&amp;A)&lt;br&gt;2. Protection from harm and ensuring validity of studies (45 minutes, including Q&amp;A)</td>
<td>1h30 min</td>
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<td>10:40 – 11:00</td>
<td><strong>Coffee break</strong></td>
<td>20 min</td>
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<td>11:00 – 12:00</td>
<td><strong>Roundtable 1: Relevance of proposals made for non-pharmaceutical biomedical research areas</strong>&lt;br&gt;Chairpersons: <strong>Fabrice GZIL</strong>, Espace Éthique Ile-de-France (France) &amp; <strong>Esperança SEVENE</strong>, Eduardo Mondlane University (Mozambique)&lt;br&gt;Panellists:&lt;br&gt;- <strong>Thomas HINAULT</strong>, INSERM (France): Social sciences&lt;br&gt;- <strong>Simon KOLSTOE</strong>, University of Portsmouth (UK): Controlled Human Infection Models&lt;br&gt;- <strong>Thérèse MURPHY</strong>, European Group on Ethics and New Technologies (EGE) &amp; Queen's University Belfast (UK): Medical Devices&lt;br&gt;- <strong>Juliet MWANGA</strong>, Epicentre Uganda Research Centre (Uganda): Epidemiology&lt;br&gt;- <strong>Raffaella RAVINETTO</strong>, Institute of Tropical Medicine, Antwerp &amp; Médecins Sans Frontières (Belgium): IRB Chair</td>
<td>60 min</td>
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<td>12:00 – 13:00</td>
<td><strong>Roundtable 2: Study sponsors and CROs</strong>&lt;br&gt;Chairpersons: <strong>Ignasi BELDA</strong>, EIT Health ELSI Board (Spain) &amp; <strong>Henri CAPLAIN</strong>, Association Française de Pharmacologie Translationnelle (AFPT) (France)&lt;br&gt;Panellists:&lt;br&gt;- <strong>Deepa ARORA</strong>, CLINEXEL (India)&lt;br&gt;- <strong>Pierre-Henri BERTOYE</strong>, UNICANCER (France)&lt;br&gt;- <strong>Yves DONAZZOLO</strong>, European Federation for Exploratory Medicines Development (EUFEMED) and the European CRO Federation (EUCROF)&lt;br&gt;- <strong>Tatjana POPLAZAROVA</strong>, GSK (Belgium)&lt;br&gt;- <strong>Nathalie SLOOTMANS</strong>, Pfizer (Belgium)&lt;br&gt;- <strong>Marta ZAKRZEWSKA</strong>, GCPpl Association and PRATIA S.A. (Poland)</td>
<td>60 min</td>
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### Roundtable 3: Regulatory agencies

**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 SEHLOLO, South African Health Products Regulatory Authority (SAHPRA) (South Africa)

### Coffee break

**15:00 – 15:15**

15 min

### SESSION 7 – Open discussion

**15:15 – 16:00**

*Open discussion, including topics for further work*

**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?*

**Next steps:**
- Irakli KHODELI, UNESCO
- Dominique SPRUMONT, Council for International Organizations of Medical Sciences (CIOMS)

**16:30 – 17:00**

*Concluding remarks*

**Concluding remarks:**
- Joanna DRAKE, Deputy Director-General, DG Research & Innovation, European Commission
- Hervé CHNEIWEISS, INSERM Ethics Committee (France)

*End of day 2*
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