Second plenary meeting of the

Volunteers in Research and Ethics (VoIREthics) 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

09:30 – 09:40 10 min	**Hervé CHNEIWEISS**, Chair of the Institut national de la santé et de la recherche médicale (INSERM) Ethics Committee (France)
09:40 – 09:50 10 min	**Irene NORSTEDT**, Director, Directorate D People, DG Research & Innovation (R&I), European Commission
09:50 – 10:00 10 min	**François HIRSCH**, INSERM Ethics Committee (France)

SESSION 1 – Healthy volunteers' involvement in research projects

10:00 – 10:05 5 min	*Introduction by the Chairs* **Maria-Filipa FERRAZ-DE-OLIVEIRA**, European Research Council Executive Agency (ERC) & **Dirk LANZERATH**, European Network of Research Ethics Committees (EUREC)
10:05 – 10:20 15 min	*Healthy volunteers in interventional biomedical research* **Ingrid KLINGMANN**, EUFEMED and European Forum for Good Clinical Practice (EFGCP)
10:20 – 10:35 15 min	*Healthy volunteers in human and social sciences research* **Juliet MWANGA**, Epicentre Uganda Research Centre (Uganda)
10:35 – 10:50 15 min	*Healthy volunteers and decentralised clinical trials: examples and points to consider* **Pierre-Henri BERTOYE**, MOH CNRIPH (France)
10 :50 – 11 :00 10 min	*Q&A*
11:00 – 11:20 20 min	**Coffee Break**

SESSION 2 – VoIREthics progress to date

11:20 – 11:25 5 min	*Introduction by the Chairs* **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 30 min	*Healthy volunteers testimonies* - **Rogers ANKUNDA** (Uganda) - **John BURWELL** (USA) - **Kaviya MANOHARAN** (India) - **Muhamad Haziq Bin MOHD MARPHY** (Malaysia) - **Bridget TAREMWA** (Uganda)
11:55 – 12:05 10 min	*Report of the first plenary meeting* **François BOMPART**, Drugs for Neglected Diseases Initiative (DNDi) (Switzerland) & INSERM Ethics Committee (France)
12:05 – 12:55 50 min	*Reports of the regional meetings* - **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 10 min	*Introduction to the parallel breakout sessions* **François BOMPART**, Drugs for Neglected Diseases Initiative (DNDi) (Switzerland) & INSERM Ethics Committee (France)
13:05 – 14:30 1h25 min	**Working lunch and continued discussion**

14:30 – 16:00 1h30 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)
16:00 – 16:30 30 min	**Coffee break & Consolidation of breakout sessions recommendations**

SESSION 4 – Keynote Lecture

16:30 – 17:00 30 min	**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 30 min	*Q&A and discussion*

DAY 2 – 25 April 2023 – 09:00 to 18:00 CET

SESSION 5 – Reporting of breakout sessions

09:00 – 09:10 10 min	*Welcome & introduction by the Chairs* **Jill FISHER**, University of North Carolina (USA) & **James A HOUGHTON**, National University of Ireland, Galway (Ireland)
09:10 – 10:40 1h30 min	*Reports of the breakout-sessions* **1.** Protection from exploitation (45 minutes, including Q&A) **2.** Protection from harm and ensuring validity of studies (45 minutes, including Q&A)
10:40 – 11:00 20 min	**Coffee break**

SESSION 6 - Roundtable discussions

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

13:00 – 13:50 50 min	**Lunch**
13:50 – 15:00 70 min	*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 SEHLOHO**, South African Health Products Regulatory Authority (SAHPRA) (South Africa)
15:00 – 15:15 15 min	**Coffee break**
SESSION 7 – Open discussion	
15:15 – 16:00 45 min	*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 30 min	*Next steps: How to progress in the elaboration of international guidelines for the protection of healthy volunteers globally?* - **Irakli KHODELI**, UNESCO - **Dominique SPRUMONT**, Council for International Organizations of Medical Sciences (CIOMS)
16:30 – 17:00 15 min	*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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