

# HACIA UN CONSENSO GLOBAL EN TRASPLANTES: DISPONIBILIDAD, TRANSPARENCIA Y REGISTRO

09-10/NOV/2023  
Reunión de Alto Nivel

## 9 DE NOVIEMBRE DE 2023

8:30 – 9:00 **REGISTRO**

9:00 – 9:15 **APERTURA INSTITUCIONAL**

9:15 – 9:35

*La donación y el trasplante en el mundo: objetivos de la reunión, metodología y resultados esperados*

Beatriz Domínguez-Gil, España

9:35 – 9:45

*Transformando el trasplante: el papel de los pacientes*

Daniel Gallego, Federación Europea de Pacientes Renales (EKPF)  
y Alianza Europa por la Salud Renal (EKHA)

9:45 - 12:00

**Moderadores:**

Elmi Muller,  
Luciano Potena

**MESA REDONDA 1: Por qué los trasplantes deben ser una prioridad sanitaria y cómo pueden contribuir a alcanzar los Objetivos de Desarrollo Sostenible de Naciones Unidas**

- **Caso 1: Hacer del trasplante una prioridad sanitaria** (15 min)  
Joel de Andrade, Brasil

- **Impacto del trasplante en salud (enfermedades no transmisibles y acceso universal a la atención sanitaria)** (20 min)  
Efstratios Chatzixiros, OMS  
Luciano Potena, Italia

- **Impacto del trasplante en otros Objetivos de Desarrollo Sostenible de Naciones Unidas** (20 min)  
Vivekanand Jha, India  
Marina Berenguer, España

- **El trasplante como parte de un sistema sanitario más resiliente** (20 min)  
Derek Manas, Reino Unido

- **Cuándo y cómo iniciar un programa de trasplante en países de bajos y medianos ingresos** (20 min)  
Elmi Muller, Sudáfrica  
Curie Ahn, Corea del Sur

- **DEBATE**

# HACIA UN CONSENSO GLOBAL EN TRASPLANTES: DISPONIBILIDAD, TRANSPARENCIA Y REGISTRO

**09-10/NOV/2023**  
**Reunión de Alto Nivel**

**12:00 - 13:00 PAUSA COMIDA**

**13:00 - 15:15**

**Moderadores:**

Matthew Cooper,  
Francis L.  
Delmonico,  
Dale Gardiner,  
Sanjay Nagral

**MESA REDONDA 2: Donación y trasplante: retos y soluciones**

- **Caso 2 : Transformar la donación de fallecido con la donación en asistolia controlada (15 min)**  
Eduardo Miñambres, España
- **Cómo promover el concepto único de muerte (20 min)**  
Francesco Procaccio, Italia
- **Cómo reducir las disparidades en la donación de personas fallecidas y aumentar la utilización de órganos (20 min)**  
Helen Opdam, Australia
- **Cómo reducir las disparidades en la donación de vivo (20 min)**  
Krista Lentine y Amy Waterman, Estados Unidos
- **Cómo reforzar la supervisión: registros de actividad y resultados tras la donación y el trasplante (20 min)**  
Michel Spiro, Reino Unido  
Dimitri A. Ratis, Arabia Saudí
- **DEBATE**

**15:15 - 15:45 PAUSA CAFÉ**

**15:45- 18:15**

**Moderadores:**

Nancy Ascher,  
Natividad Cuende,  
Stefan Tullius

**MESA REDONDA 3: Innovación en la donación y aplicación clínica de sustancias de origen humano (SoHO): células y tejidos**

- **Caso 3: Terapia celular para la inducción de tolerancia inmunológica (15 min)**  
Rafael Correa, España
- **Cuando las SoHO se convierten en medicamentos y productos sanitarios: límites e implicaciones regulatorias (20 min)**  
Ander Izeta, España
- **Cómo abordar la eficacia y seguridad antes de que la innovación llegue a la clínica (20 min)**  
Verena Plattner, Austria

# HACIA UN CONSENSO GLOBAL EN TRASPLANTES: DISPONIBILIDAD, TRANSPARENCIA Y REGISTRO

**09-10/NOV/2023**  
**Reunión de Alto Nivel**



PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

- **Cómo hacer la innovación sostenible para los sistemas sanitarios** (20 min)

Martin Börgel, Alemania

- **Alianzas público-privadas para hacer la innovación accesible a los pacientes** (20 min)

Rachele Ciccocioppo, Italia

- **DEBATE**

**19:30 - 20:30**      **EVENTO SOCIAL**

**20:30 - 22:30**      **CENA**

## **10 DE NOVIEMBRE DE 2023**

**8:30 - 9:10**

**Moderadores:**

Nancy Ascher,  
Natividad Cuende,  
Stefan Tullius

**MESA REDONDA 3: Innovación en la donación y aplicación clínica de sustancias de origen humano (SoHO): órganos**

- **Cómo abordar la innovación en la donación y el trasplante de órganos** (20 min)

Gabriel Oniscu, Suecia

- **DEBATE**

**9:10 - 11:40**

**Moderadores:**

John Forsythe,  
Marta López-Fraga,  
Dominique Martin

**MESA REDONDA 4: Problemas éticos y hoja de ruta para impulsar los Principios Rectores del Trasplante de la Organización Mundial de la Salud**

- **Caso 4 : Crisis y trasplante** (15 min)

Dominique Martin, Australia

- **Cómo garantizar la equidad en el acceso a las terapias basadas en SoHO** (20 min)

Esteve Trias, España

- **Cómo abordar el acceso al trasplante cuando los pacientes cruzan fronteras** (20 min)

Thomas Mueller, Suiza

# HACIA UN CONSENSO GLOBAL EN TRASPLANTES: DISPONIBILIDAD, TRANSPARENCIA Y REGISTRO

**09-10/NOV/2023**  
**Reunión de Alto Nivel**

- **Cómo hacer realidad el principio de neutralidad económica en la donación** (20 min)

Benita Padilla, Filipinas

- **Cómo prevenir el tráfico de órganos y otras sustancias de origen humano (SoHO)** (20 min)

Riadh Fadhil, Qatar

- **DEBATE**

**11:40 - 12:10**

## **SESIÓN FINAL: Mirando al futuro**

### **Moderadores:**

Efstratios Chatzixiros,  
Beatriz Domínguez-Gil

- **La Declaración de Santander**

Alicia Pérez Blanco, España

Kristof Van Assche, Bélgica

**12:10 - 12:30 PAUSA CAFÉ**

**12:30 - 13:45**

## **MESA REDONDA *El trasplante: una visión a 10 años***

- **Gabriel Oniscu**

Presidente, European Society for Organ Transplantation

- **Elmi Muller**

Presidenta, The Transplantation Society

- **Stefaan Van der Spiegel**

Jefe del área de sustancias de origen humano, Comisión Europea

- **Nicolás González Casares**

Diputado español, Parlamento Europeo

- **Petra Doerr**

Directora EDQM, Consejo de Europa

- **Yukiko Nakatami**

Directora general adjunta, Organización Mundial de la Salud

## **CIERRE INSTITUCIONAL**

- **Marija Bubas**

Secretaria de Estado de Sanidad, Croacia

- **Carla Vizzotti**

Ministra de Salud, Argentina

- **José Miñones**

Ministro de Sanidad, España

**13:45**

**COMIDA**

# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

**09-10/NOV/2023**  
**High Level Meeting**



PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

## NOVEMBER 9TH 2023

8:30 – 9:00

REGISTRATION

9:00 – 9:15

INSTITUTIONAL OPENING

9:15 – 9:35

*Overview of donation and transplantation in the world: aims of the meeting, methodology and expected outcomes*

Beatriz Domínguez-Gil, Spain

9:35 – 9:45

*Patient-driven transformations in transplantation*

Daniel Gallego, European Kidney Patients Federation and European Kidney Health Alliance

9:45 - 12:00

Chairs:

Elmi Muller,  
Luciano Potena

**ROUND TABLE 1: Why transplantation should be a priority in the health-care agenda and how can transplantation contribute to attaining the United Nations Sustainable Development Goals**

- **Case study 1: Making transplantation a health-care priority (15 min)**  
Joel de Andrade, Brazil

- **The impact of transplantation upon health (non-communicable diseases & universal access to health) (20 min)**  
Efstratios Chatzixiros, WHO  
Luciano Potena, Italy

- **The impact of transplantation upon other United Nations Sustainable Development Goals (20 min)**  
Vivekanand Jha, India  
Marina Berenguer, Spain

- **Transplantation as part of more resilient health-care systems (20 min)**  
Derek Manas, UK

- **When and how to start a transplantation program in a low resource environment (20 min)**  
Elmi Muller, South Africa  
Curie Ahn, South Korea

- **DISCUSSION**

# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023  
High Level Meeting

U  
23

PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

12:00 - 13:00 LUNCH BREAK

13:00 - 15:15

**Chairs:**

Matthew Cooper,  
Francis L.  
Delmonico,  
Dale Gardiner,  
Sanjay Nagral

**ROUND TABLE 2: *Donation and transplantation: challenges and way forward***

- **Case study 2: Transforming deceased donation through donation after the circulatory determination of death** (15 min)

Eduardo Miñambres, Spain

- **Promoting the unified concept of death** (20 min)

Francesco Procaccio, Italy

- **Reducing disparities in deceased donation and increasing organ utilization** (20 min)

Helen Opdam, Australia

- **Reducing disparities in living donation** (20 min)

Krista Lentine & Amy Waterman, United States

- **Reinforcing oversight: activity monitoring and registries of post-donation and post-transplant outcomes** (20 min)

Michel Spiro, UK

Dimitri A. Ratis, Saudi Arabia

- **DISCUSSION**

15:15 - 15:45 COFFEE BREAK

15:45- 18:15

**Chairs:**

Nancy Ascher,  
Natividad Cuende,  
Stefan Tullius

**ROUND TABLE 3: *Innovation in the donation and clinical application of substances of human origin (SoHO): cells & tissues***

- **Case Study 3: Cell therapy to induce tolerance** (15 min)

Rafael Correa, Spain

- **When SoHO become medicines and medical devices: regulatory borderlines and implications** (20 min)

Ander Izeta, Spain

- **Addressing clinical efficacy and safety before innovation reaches the bedside** (20 min)

Verena Plattner, Austria

# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

**09-10/NOV/2023**  
**High Level Meeting**



PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

- 
- **Making innovation sustainable for health-care systems** (20 min)  
Martin Börgel, Germany
  - **Public-private partnerships to make innovation accessible to patients**  
(20 min)  
Rachele Ciccocioppo, Italy
  - **DISCUSSION**

**19:30 - 20:30 SOCIAL EVENT**

**20:30 - 22:30 DINNER**

---

## **NOVEMBER 10TH 2023**

**8:30 - 9:10**

**Chairs:**

Nancy Ascher,  
Natividad Cuende,  
Stefan Tullius

**ROUND TABLE 3: Innovation in the donation and clinical application of substances of human origin (SoHO): organs**

- **Addressing innovation in organ donation and transplantation** (20 min)  
Gabriel Oniscu, Sweden
- **DISCUSSION**

**9:10 - 11:40**

**Chairs:**

John Forsythe,  
Marta López-Fraga,  
Dominique Martin

**ROUND TABLE 4: Ethical challenges and the way forward to implement the WHO Guiding Principles**

- **Case Study 4: Crisis and transplantation** (15 min)  
Dominique Martin, Australia
- **Promoting equity in access to SoHO-based therapies** (20 min)  
Esteve Trias, Spain
- **Promoting fairness in access to transplantation when people cross borders** (20 min)  
Thomas Mueller, Switzerland

# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023  
High Level Meeting

U  
23

PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

- **Making financial neutrality in donation a reality** (20 min)  
Benita Padilla, Philippines

- **Preventing trafficking in organs and other SoHO** (20 min)  
Riadh Fadhil, Qatar

- **DISCUSSION**

**11:40 - 12:10**

## FINAL SESSION

**Chairs:**

Efstratios Chatzixiros,  
Beatriz Domínguez-Gil

- **The Santander Statement**  
Alicia Pérez Blanco, Spain  
Kristof Van Assche, Belgium

**12:10 - 12:30 COFFEE BREAK**

**12:30 - 13:45**

## ROUND TABLE: A vision of transplantation 10 years ahead

- **Gabriel Oniscu**

President, European Society for Organ Transplantation

- **Elmi Muller**

President, The Transplantation Society

- **Stefaan Van der Spiegel**

Head of Sector, Substances of Human Origin (SoHO), European Commission

- **Nicolás González Casares**

Member, European Parliament

- **Petra Doerr**

EDQM Director, Council of Europe

- **Yukiko Nakatami**

Assistant Director-General, World Health Organization

## **INSTITUTIONAL CLOSING**

- **Marija Bubas**

State Health Secretary, Croatia

- **Carla Vizzotti**

Health Minister, Argentina

- **José Miñones**

Health Minister, Spain

**13:45**

**LUNCH**



# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023

High Level Meeting

U  
23

PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

## CHAIRS & SPEAKERS

(in alphabetical order)

### **Curie Ahn**

Nephrologist, National Medical Center  
Seoul, Korea

### **Nancy L. Ascher**

Past President, The Transplantation Society  
Isis Distinguished Professor of Transplantation  
Professor of Surgery, University of California  
San Francisco, California, US

### **Marina Berenguer Haym**

Hepatology and Liver Transplant Unit,  
Hospital Universitari i Politècnic La Fe,  
Ciberehd, Instituto de Investigación Sanitaria,  
University of Valencia,  
Valencia, Spain

### **Martin Börgel**

CEO, German Society for Tissue Transplantation  
President elect, European Association of Tissue and Cell Banks  
Secretary General, World Union of Tissue Banking Associations  
Hannover, Germany

### **Efstratios (Stratos) Chatzixiros**

Adviser, Transplantation Human Organs-Tissues-Cells  
Blood and Other Products of Human Origin team  
Health Product Policy and Standards department  
WHO Headquarters  
Geneva, Switzerland

### **Rachele Ciccocioppo**

Associate Professor in Gastroenterology  
Gastroenterology Unit, Department of Medicine  
A.O.U.I. Policlinico G.B. Rossi & University of Verona  
Verona, Italy

### **Matthew Cooper**

Mark B. Adams Chair in Transplant Surgery  
Chief, Division of Transplant Surgery  
Director, Solid Organ Transplant Service Line  
Froedtert Memorial Lutheran Hospital  
Director, Solid Organ Transplantation  
Children's Wisconsin  
Tenured Professor of Surgery  
Medical College of Wisconsin  
Milwaukee, Wisconsin, US

### **Natividad Cuende Melero**

Deputy Director of the Andalusian Transplant Coordination  
Andalusian Health Service  
Seville, Spain

### **Rafael Correa Rocha**

Founder Chief of the Laboratory of Immune-regulation  
Instituto de Investigación Sanitaria Gregorio Marañón  
Founder Director, THYTECH SL  
Madrid, Spain

### **Joel de Andrade**

State Transplant Coordinator  
Santa Catarina Health Authority  
Florianopolis, Brazil

### **Francis L. Delmonico**

Professor of Surgery, Harvard Medical School  
Massachusetts General Hospital, Transplantation Center  
Chief Medical Officer, New England Donor Services  
World Health Organization  
Advisor Organ Transplantation  
Pontifical Academy of Sciences  
Boston, Massachusetts, US

### **Beatriz Domínguez-Gil González**

General Director  
Organización Nacional de Trasplantes (ONT)  
Ministry of Health  
Spain

### **Riadh A. S. Fadhil**

Professor of Urology & Transplant Surgery  
Director of Qatar Organ Donation Center  
Hamad Medical Corporation/ Weill Cornell College of Medicine-Q  
Doha, Qatar

### **John Forsythe**

Chair of the Ethics Committee and Council Member, The Transplantation  
Society  
United Kingdom

### **Daniel Gallego Zurro**

President European Kidney Patients Federation  
Board of Direction member European Kidney Health Alliance  
Spain

### **Dale Gardiner**

Associate Medical Director  
Deceased Organ Donation  
NHS Blood and Transplant  
United Kingdom

### **Ander Izeta Permisán**

Advanced Therapies Unit  
Donostia University Hospital  
Donostia-San Sebastián, Spain

### **Vivekanand Jha**

George Institute for Global Health, India  
School of Public Health, Imperial College  
London, United Kingdom

### **Krista Lentine**

SSM Health-Saint Louis University Transplant Center  
St. Louis, Missouri, US

### **Marta López Fraga**

Scientific Programme Manager  
Organ Transplantation  
Department of Biological Standardisation, OMCL Network & HealthCare.  
EDQM, Council of Europe  
Strasbourg, France

# TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023  
High Level Meeting



PRESIDENCIA  
ESPAÑOLA  
CONSEJO DE LA  
UNIÓN EUROPEA

## CHAIRS & SPEAKERS

(in alphabetical order)

### **Derek M Manas**

Medical Director Organ & Tissue Donation & Transplantation  
NHS Blood and Transplant  
United Kingdom

### **Dominique Martin**

Professor in Health Ethics and Professionalism  
School of Medicine, Faculty of Health  
Deakin University Australia  
Australia

### **Eduardo Miñambres García**

Intensivist and Head of the Transplant Coordination Unit  
Marqués de Valdecilla University Hospital  
Associate Professor in Surgery at University of Cantabria  
Santander, Spain

### **Thomas F Mueller**

Professor of Medicine  
Director a.i., Clinic of Nephrology  
Medical Lead of the Renal Transplant Program  
Co-chair, Declaration of Istanbul Custodian Group  
University Spital of Zurich  
Zurich, Switzerland

### **Elmi Muller**

President, The Transplantation Society  
Dean at University of Stellenbosch, Faculty of Medicine and Health  
Sciences  
City of Cape Town, Western Cape, South Africa

### **Sanjay Nagral**

Director Department of Surgical Gastroenterology  
Jaslok Hospital & Research Center  
Co-Chair, Declaration of Istanbul Custodian Group  
Mumbai, India

### **Gabriel C Oniscu**

President, European Society for Organ Transplantation  
Chair of Transplantation Surgery  
Head of Transplant Division  
Department of Clinical Science, Intervention and Technology  
Karolinska Institutet  
Stockholm, Sweden

### **Helen Opdam**

Intensive Care Specialist, Austin Hospital  
Director of Intensive Care, Warringal Private Hospital  
National Medical Director, Australian Organ and Tissue Authority  
President, International Society for Organ Donation and Procurement  
Australia

### **Benita Padilla**

National Kidney and Transplant Institute  
Philippines

### **Alicia Pérez Blanco**

Intensivist. Medical Officer  
Organización Nacional de Trasplantes (ONT)  
Ministry of Health  
Spain

### **Verena Plattner**

Austrian Federal Office for Safety in Healthcare (BASG/AGES MEA)  
Head of Department Blood, Tissue & Vigilance  
Austria

### **Luciano Potena**

Past President, European Society for Organ Transplantation  
Director Heart Failure and Transplant Unit  
IRCCS Azienda Ospedaliero-Universitaria di Bologna  
Bologna, Italy

### **Francesco Procaccio**

Advisor, National Transplant Centre Roma  
National DCD Project, ANED Milan  
Former Director, Neuro ICU Dpt.  
University City Hospital of Verona  
Verona, Italy

### **Dimitri Aristotle Raptis**

Consultant HPB and Liver Transplant Surgeon  
Lead of the Analytics Data Unit, Organ Transplant Center of Excellence  
King Faisal Specialist Hospital and Research Center  
Riyadh, Saudi Arabia

### **Michael Spiro**

Consultant in Anaesthesia and Liver Intensive Care Medicine  
The Royal Free NHS Foundation Trust  
Associate Professor. The Division of Surgery  
University College London  
London, United Kingdom

### **Esteve Trias**

Technical Director  
Advanced Therapies Unit, Hospital Clinic of Barcelona  
Executive Medical Director, Leitat Technological Center  
Barcelona, Spain

### **Stefan G. Tullius**

Joseph E. Murray, MD Distinguished Chair in Transplant Surgery  
Chief, Division of Transplant Surgery  
Professor of Surgery, Harvard Medical School  
Brigham and Women's Hospital  
Boston, Massachusetts, US

### **Kristof Van Assche**

Research Professor in Health Law  
University of Antwerp  
Antwerp, Belgium

### **Stefaan Van der Spiegel**

Head of Sector. Substances of Human Origin (SoHO)  
European Commission  
DG SANTE (Health and Food Safety)  
Unit B4 – Medical Products: quality, safety, innovation

### **Amy D. Waterman**

Director, Patient Engagement, Diversity, and Education  
Professor of Outcomes Research  
Houston Methodist Department of Surgery and J.C. Walter Jr.  
Transplant Center  
Houston, Texas, US