STEERING COMMITTEE

National Transplant Centre, Italy (Project Co ordinator)
Donor Action Foundation, Belgium
Irish Medicines Board
National Transplant Organisation, Spain
Biomedicine Agency, France
French Agency for the Safety of Health Products
National Centre for Tissue and Cell Banking, Poland
Human Fertilisation and Embryology Authority, UK
Human Tissue Authority, UK
World Health Organisation, Switzerland

COLLABORATING PARTNERS

Paul-Ehrlich-Institute, Germany; University Hospital Bratislava, Central Tissue Bank, Slovakia; Ministry of Health and Social Welfare, Croatia; Executive Agency of Transplantation, Bulgaria; Italian Assisted Reproduction Registry; Danish Medicines Agency; Health Care Inspectorate Medicines and Medical Technology, the Netherlands; Federal Ministry of Health, Austria; Food and Drug Administration, United States; Blood Safety Surveillance and Health Care Acquired Infections Division Centre for Communicable Disease and Infection Control, Public Health Agency of Canada; Tissue and Cell Inspectorate, Cyprus; Slovenia-transplant; Transfusion Reactions in Patients, the Netherlands; Office of Blood, Organ and other Tissue Safety, Division of Healthcare Quality Promotion, Centres for Disease Control and Prevention, United States; Department of Pathology and Laboratory Medicine & McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, Canada; European Association of Tissue Banks; American Association of Tissue Banks; European Society for Human Reproduction and Embryology; European Eye Banking Association; European Society for Bone Marrow Transplantation; Public Health Agency, UK; International Haemovigilance Network Ministry of Health, Malta; AABB; World Marrow Donor Association.

KEY PROJECT EVENTS

- **International workshop on vigilance in Assisted Reproduction Technologies (ART)**
  France, 2010
- **International workshop on the investigation and management of serious adverse events and reactions in tissues and cells**
  Italy, 2011
- **Consultation with professional groups to discuss the promotion of vigilance and surveillance at the clinical user level**
  Poland, 2011
- **Investigation guidelines focus group consultations**
  Germany, Spain and UK, 2011
- **Training courses for vigilance and surveillance officers**
  Ireland and Italy, 2012
- **Global vigilance and surveillance conference**
  UK, 2012

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VIGILANCE AND SURVEILLANCE OF SUBSTANCES OF HUMAN ORIGIN

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VIGILANCE AND SURVEILLANCE OF SUBSTANCES OF HUMAN ORIGIN – SOHO V&S

SOHO V&S is a three-year project co-funded by the European Commission Public Health Programme and the project's Associated Partners.

AIM

The project's primary aim is to support the establishment of effective vigilance and surveillance systems for tissues and cells used in transplantation and in assisted reproduction.

BACKGROUND

Human tissues and cells circulate throughout the EU, and often globally, on a significant scale. This project is working to develop a shared view of how serious adverse events and reactions, associated with tissue and cell donation or human application, are reported, evaluated and investigated.

Through collaboration between regulators and professionals, the project is addressing the harmonisation of terminology, documentation and a consensus on how information should be exchanged between EU Member States, the European Commission and third countries, to enhance efficient management of incidents involving cross-border distribution of tissues and cells.

The involvement of the World Health Organisation and other collaborating partners from outside the EU ensures that the guidance produced in this project reflects international needs and realities. It is intended that the guidance will enhance cross-border communication and the management of serious adverse events and reactions worldwide.

PROJECT OUTCOMES

- Guidance on the investigation and management of serious adverse events and reactions in tissues and cells.
- Guidance on vigilance and surveillance in the field of assisted reproduction.
- Guidance on the investigation, communication and control of illegal and fraudulent activity.
- A report on vigilance of living donors.
- Increased transparency through enhancement of the Eurocet platform (www.eurocet.org) to incorporate vigilance and surveillance information.
- Training courses for EU Competent Authority vigilance and surveillance officers with a 6 week e-learning module and 3 day residential module.
- A practical guidance document promoting vigilance and surveillance at the clinical user level