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Vigilance and Surveillance of Substances of Human Origin

JA2015 - GPSD [705038]

START DATE: 01/03/2010

END DATE: 01/03/2013

DURATION: 36 month(s)

CURRENT STATUS: Finalised

PROGRAMME TITLE: Second Programme of Community action in the Field of Health 2008-2013

PROGRAMME PRIORITY: -

CALL: Improve Citizen'S Health Security (Hs-2009)

TOPIC: IMPROVE CITIZEN'S HEALTH SECURITY (HS-2009)

EC CONTRIBUTION: 794313 EUR

KEYWORDS: Tissue, cell and organ transplants, Tissues and Cells

PORTFOLIO: Tissues and Cells

General objectives

The aim of SOHOV&S is to support EU MS in the establishment of Vigilance and Surveillance (V&S) systems for tissues and cells in transplantation and in assisted reproduction. MS with most experience will facilitate less experienced in the implementation of systems. The guidance can be translated and used as basis for national procedures. The training will ensure that officials who have recently been given these responsibilities will quickly be able to fulfil them. The project will drive harmonisation in terminology, investigation approaches, facilitating communication and cross-border management of serious adverse events and reactions (SAR/E). WHO involvement will extend this outcome to a global scale. The training will provide EU investigators to react effectively and efficiently to SAR/E. The guidelines for clinical users will support MS in the efforts to inform clinicians of roles and responsibilities in relation to V&S. Awareness on V&S will be raised via the project website and the enhancement of the Eurocet platform to include data on V&S activities.

Strategic relevance and contribution to the public health programme

This project is working to develop a shared view of how SAR/E, associated with tissue and cell donation or human application, are reported, evaluated and investigated. Tissues and cells for human application represent one of the key areas where the EU has introduced legislation to protect public health. It requires MS to establish systems for reporting of SAR/E and for forwarding an annual report of this activity to the Commission. The Work Plan for 2009 for the implementation of the second programme of Community action in the field of health (2008 to 2013) at 3.2.2.4. stated that `On blood and tissues and cells specific questions remain on the reporting systems and rapid response to serious adverse events and reactions and coding. Projects will be prioritised to help developing methodologies in this area`. Thus, this project is entirely in line with the Health Programme Work Plan.

Methods and means

The project objectives will be achieved using a number of different methods.

The guidance will include:

- interactive brain-storming and case study in exploratory workshops
- questionnaire survey on the current situation
- consultation with experts and stakeholders
- review of national or international guidance

Training will be delivered using:

- an e-learning platform (50 - 60 hours)
- 2 day residential courses.

Global networking will be achieved using:

- invitation of third country experts to key events
- consultation with key third country regulators on draft documents
- publication and presentation at international meetings
- a conference with discussions, posters and workshops.

Dissemination will be achieved using:

A website with e-newsletters, enhancement of the Eurocet platform to include V&S information, journals, guidance documents, conferences, a brochure and a guidance booklet for hospitals and clinics.

Management will be achieved by regular meetings, reports, email correspondence, teleconferencing and sharing of documents on the reserved area of the website.

Expected outcomes period

At community level, there will be a shared view of how SAR/E should be investigated and reported. An EU network of officers and investigators will enhance management of incidents involving cross-border distribution of tissues and cells. MS will have a shared strategy for investigating, managing and communicating illegal and fraudulent activity. At national level, MS setting up new V&S systems in the field will have guidelines as basis of their procedures and policies. For the general public, there will be enhanced transparency in the risks associated with tissue and cell transplantation and assisted reproduction with information available on enhanced Eurocet platform. The promotion of the organisations monitoring vigilance programmes will increase confidence. From a global perspective, the WHO will be able to use the principles to promote V&S in the field of tissues and cells and to support this aspect of developing regulatory programmes around the world.

COORDINATOR

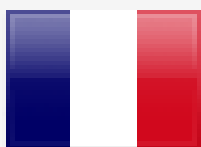


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Viale Regina Elena 299
00161 Roma

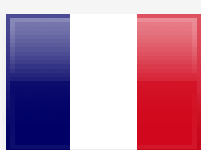
Italy

PARTNERS



Agence de la Biomedecine
Street: 1 avenue du Stade de France
City: 93212 Saint-Denis La Plaine Cedex

Country: France



Agence Française de Sécurité Sanitaire des Produits de Santé
Street: 143/147 boulevard Anatole France, 93285 Saint-Denis
Cedex
City: 93285 Saint Denis

Country: France



Krajowe Centrum Bankowania Tkanek i Komorek
Street: Chalubinskiego 5
City: 02-005 Warsaw

Country: Poland

The Human Fertilisation and Embryology Authority
Street: 21 Bloomsbury Street
City: WC1B 3HF London



Country: United Kingdom



Human Tissue Authority
Street: Finlaison House, 15-17 Furnival Street
City: EC4A 1AB London

Country: United Kingdom



Donor Action Foundation
Street: Prinsendreef 10
City: 3210 Linden

Country: Belgium



Irish Medicines Board
Street: Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace
City: Dublin 2 Dublin

Country: Ireland



Organisacion Nacional de Trasplantes
Street: SINESIO DELGADO, 6-8. PABELLÓN 3
City: 28029 Madrid

Country: Spain

D01-01 - Interim implementation, financial, dissemination and evaluation report (EN)

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Vigilance and Surveillance of Substances of Human Origin (SOHOV&S)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d01_oth_en_is_01.pdf

D01-02 - Interim implementation, financial, dissemination and evaluation report (EN)

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D02-01 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-03 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-04 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-05 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-06 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-07 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-08 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_ffr_en_is_08.pdf

D02-09 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_ffr_en_is_09.pdf

D02-10 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-11 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-12 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-13 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-14 - Final implementation, financial, dissemination and evaluation report (EN)

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D02-15 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_nwl_en_ps_01.pdf

D02-16 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_nwl_en_ps_02.pdf

D02-17 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_nwl_en_ps_03.pdf

D02-18 - Final implementation, financial, dissemination and evaluation report (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d02_nwl_en_ps_04.pdf

D03 - Project Information Brochure

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D04 - Survey Report (EN)

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D05 - Guidance Document on V&S in ART in

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d05_oth_en_ps.pdf

D06 - Report on serious adverse reactions in living donors of tissues and cells. (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d06_oth_en_ps.pdf

D07 - Guidance on Illegal and Fraudulent Activity in Tissues and Cells (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d07_oth_en_ps.pdf

D08 - Guidance Document on investigation and communication of SAE/R (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d08_oth_en_ps.pdf

D09 - Training course model for investigators of SAE/R (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d09_oth_en_ps.pdf

[_en_ps.pdf](#)

D10-01 - V&S Guidance for Clinical Units (EN)

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http://persond.cc.cec.eu.int:8082/publications/20091110/20091110_d10_oth_en_ps_01.pdf

D10-02 - V&S Guidance for Clinical Units (EN)

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Internal Assessment Note (EN)

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