VISTART
VIGILANCE AND INSPECTION FOR THE SAFETY OF TRANSFUSION ASSISTED REPRODUCTION AND TRANSPLANTATION

This Joint Action (JA) is meant to support EU Member States (MS) in developing and strengthening their capacity for monitoring and control in the field of blood, tissues and cells transplantation. The key objectives are to promote and to facilitate the harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells and to increase inter-MS collaboration and confidence in each other's inspection and vigilance programmes.

Coordination

WP1 leader: Istituto Superiore di Sanità (ISS)

ISS, HNBTS, RNDVCSH, IPST, ANSM, MOH RC - HR, HPRA, E.KE.A, AGES-MEA, FAMHP, BEAT, MOH LT - LT, HDIR, IHTM, NCK, KCBTiK, ANT

The JA Management will monitor the activity of all partners involved in the project and the outputs of the project. It will control both quality and timing of the activities in order to avoid any major gaps between what was planned and the work actually performed. It will establish breakpoints at which to check and assess progress, and will decide how both progress and results will be measured.

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Communication and Public Awareness

WP2 leader: Hungarian National Blood Transfusion Service (HNBTS)

HNBTS, ISS, RNDVCSH, IPST, ANSM, HPRA, E.KE.A, AGES-MEA, FAMHP, BEAT, HDIR, IHTM, NCK, KCBTiK, ANT

This WP is responsible for the dissemination of the initiative with the aim of showing the goals achieved and the different results of the project, in accordance with their level of confidentiality defined in the Grant Agreement. This group cares the website and edits the layman brochures to inform cross-border the Countries.
The national and international communication (congress atttendance, articles, lectures) will be the most important technique to introduce the results of the working groups on the harmonised quality, inspection vigilance system of blood and tissues and cells establishments.

Evaluation

WP3 leader: National Register of Hematopoietic Stem Cells Voluntary Donors from Romania (RNDVCSH)

RNDVCSH, ISS, HNBTS, IPST, ANSM, HPRA, E.KE.A, AGES-MEA, FAMHP, BEAT, HDIR, IHTM, NCK, KCBTiK, ANT

This WP aims to ensure that the project is being implemented as planned, reaches its objectives and that high quality deliverables are produced. The actions undertaken in WP3 consist in the monitoring and feed-back on all performed activities within the WPs. Their tools are the questionnaires, monitoring the events. In addition, an evaluation of whether the project outputs are fit for purpose will be carried out.

Vigilance reporting for blood, tissues and cells

WP4 leader: Portuguese Blood and Transplantation Institute (IPST)

IPST, ISS, HNBTS, RNDVCSH, ANSM, HPRA, AGES-MEA, FAMHP, HDIR, IHTM, NCK, KCBTiK

The WP aims to explore commonalities between vigilance in blood, tissues and cells areas, identifying opportunities for sharing of information and procedures to improve safety and quality across blood, tissues, cells, assisted reproduction. The key objective is to harmonize the work in the areas of annual SARE reporting, of Rapid Alert procedures and of horizon scanning for identifying new risks.

International collaboration for Vigilance Communication and new Preparation Process

WP5 leader: Italian National Transplant Centre (ISS)

ISS, HNBTS, RNDVCSH, IPST, KCBTiK

The main aim of this WP is increasing the sharing of vigilance and clinical outcome information between Member States in order to achieve higher standards of safety and quality across blood, tissues and cells. To this purpose, the use of tools such as the NOTIFY Library is going to be promoted and incentivated among EU Competent Authorities. Furthermore, the WP will propose harmonized standards for the evaluation of quality/safety and of clinical outcome of newly developed blood, tissues and cells products.

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Inspection Guidelines

WP6 leader: Agence Nationale de sécurité du Médicament et des produits de santé (ANSM)

ANSM, ISS, HNBTS, RNDVCSH, HPRA

The main objective of this WP is to prepare final inspection guidelines for the EU Competent Authorities who are responsible for the inspection and authorization of blood and tissue establishments. This document aims at identifying a common framework for the conduction of inspections of blood and tissue establishments, to be achieved through the analysis of overlapping approaches and development of a common approach with sharing of procedures across Member States.

Training of blood, tissues, cells inspectors with sharing of expertise across Member States

WP7 leader: Italian National Blood Centre (ISS)

ISS, HNBTS, RNDVCSH, ANSM, HPRA, E.KE.A, BEAT, IHTM, NCK, KCBTiK, ANT

This WP will assess, through a survey, the educational profile, basic competences and specific skills required by MSs for the respective inspectors in the field of blood, tissues and cells.

On the basis of the results of the survey, the main objectives of this WP will be the design and deliver of two specialist blended learning courses for blood, tissues and cells, ART inspectors, based on the work of EUSTITE, EUBIS, CATIE and ARTHIQS, as well as taking into account the guidelines developed by WP6. In addition, proposals for the acceptance of inspectors in an EU register of international inspectors will be after formulated. This register could be the basis for the creation of joint inspection teams (WP8).

Establishment of a Framework for Joint Inspections

WP8 leader: Ministry of Health of Croatia (MOH RC-HR)

MOH RC-HR, ISS, HNBTS, RNDVCSH, ANSM, AGES-MEA, BEAT, MOH LT-LT, ANT

The WP will explore specific situations in which one MS may wish to inspect a blood or tissue establishment or a third party supplier in another MS or a third country or two or more MS wish to develop multi-country inspection teams. Partners in WP will perform real on-site inspections and, based on experience gained, develop the Code of Practice for multi-country joint inspections. The main objective of the WP is promoting harmonised inspection bodies' cooperation and support.

A Voluntary Programme of Inter-Member State Inspection Systems Auditing

WP9 leader: Health Products Regulatory Authority, Ireland (HPRA)

HPRA, ISS, HNBTS, RNDVCSH, ANSM

The WP goal is to support Member States in verifying the equivalence of each others Blood & Tissues and Cells Inspection Systems according to the implemention of the recommendations of PIC/S Joint Audit programme and CA experience with BEMA.

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Implementation of the Single European Coding System in Tissue establishments

WP10 leader: Italian National Transplant Centre (ISS)

ISS, HNBTS, RNDVCSH, IPST, ANSM, BEAT, HDIR, KCBTiK, ANT

This WP is meant to support Member States in implementing tissues and cells traceability as foreseen by EU regulation. Dissemination activities concerning Single European Code (SEC) working, how this interacts with local, national or international coding systems are going to be performed. Furthermore an e-learning course and onsite visits will be carried out, with the aim of supporting Competent Authorities and tissue establishments in SEC use. As desireable result, a harmonised and more efficient implementation of the new provisions with considerably improved traceability of tissues and cells throughout the European Union will be ensured.

WPs Steering Committee

WP number	Title	Leader (Acronym)
1	Management of the action	Istituto Superiore di Sanità - Centro Nazionale Trapianti - Centro Nazionale Sangue (ISS-CNT-CNS)
2	Dissemination	Országos Verellató Szolgálat (OVSZ/HNTBS)
3	Evaluation	Registrul National al Donatorilor Voluntari de Celule Stem Hematopoietice (NRSCDVH)
4	Vigilance reporting for blood tissues and cells	Instituto Portugues do Sangue e da Transplantacao (IPST)
5	International collaboration for vigilance communication and preparation process development	Istituto Superiore di Sanità - Centro Nazionale Trapianti (ISS-CNT)
6	Inspection guidelines for blood, tissues and cells Competent Authorities	Agence Nationale de Securite du Medicament et des Produits de Sante (ANSM)
7	Training of blood, tissues, cells and ART inspectors with sharing of expertise across Member States	Istituto Superiore di Sanità - Centro Nazionale Sangue (ISS-CNS)
8	Establishment of a framework for joint inspections	Ministarstvo Zdravlja Republike Hrvatske (MOH RC)
9	A voluntary programme of Inter-MS Inspection	Auditing Health Products Regulatory Authority (HPRA)
10	Implementation of the Single European Coding system in tissue establishments	Istituto Superiore di Sanità - Centro Nazionale Trapianti (ISS-CNT)

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Coordinator

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Associated Partners

(AGES-MEA) BUNDESAMT FUER SICHERHEIT IM GESUNDHEITSWESEN, Austria

(ANSM) AGENCE NATIONALE DE SECURITE DU MEDICAMENT ET DES PRODUITS DESANTE, France

(ANT) AGENTIA NATIONALA DE TRANSPLANT, Romania

(BEAT) EXECUTIVE AGENCY FOR TRANSPLANTATION,Bulgaria

(E.KE.A) HELLENIC NATIONAL BLOOD TRANSFUSION CENTRE, Greece

(FAMHP) FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS, Belgium

(HDIR) HELSEDIREKTORATET, Norway

(HNBTS) ORSZAGOS VERELLATO SZOLGALAT, Hungary

(HPRA) HEALTH PRODUCTS REGULATORY AUTHORITY, Ireland

(IHTM) INSTYTUT HEMATOLOGII I TRANSFUZJOLOGII, Poland

(IPST) INSTITUTO PORTUGUES DO SANGUE E DA TRANSPLANTACAO, Portugal

(KCBTiK) KRAJOWE CENTRUM BANKOWANIA TKANEK I KOMOREK, Poland

(MOH LT-LT) LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA, Lithuania

(MOH RC-HR) MINISTARSTVO ZDRAVLJA REPUBLIKE HRVATSKE, Croatia

(NCK) NARODOWE CENTRUM KRWI, Poland

(RNDVCSH) REGISTRUL NATIONAL AL DONATORILOR VOLUNTARI DE CELULE STEM HEMATOPOIETICE, Romania

GRANT
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Collaborating stakeholders

Agence de la biomédecine, Paris, France

Belgian Red Cross (Rode Kruis Vlaanderen), Mechelen, Belgium

Bulgarian Drug Agency, Sofia, Bulgaria

Centro de Hemoterapia y Hemodonación de Castilla y León, Valladolid, Spain

Croatian Institute for Transfusion Medicine, Zagrab, Croatia

Danish Health and Medicines Authority, Copenhagen, Denmark

EuBIS Accademy, Frankfurt Am Mein, Germany

European Centre for Disease Control, Stockholm, Sweden

The Finnish Medicines Agency, Helsinki, Finland

Hellenic National Coordinating Haemovigilance Centre, Athens, Greece

Human Tissue Authority, London, UK

Landspitali University Hospital, Reykjavik, Iceland

Ministry for Energy and Health, Malta - Directorate for Healthcare Standards, Valletta, Malta

Ministry of Health and Inspectorate of Montenegro, Podgoriza, Montenegro

Ministry of Health Cyprus, Nicosia, Cyprus

The Ministry of Health, Bratislava, Slovak Republic

National Centre on Transfusion Haematology, Sofia, Bulgaria

Organización Nacional de Transplantes, Madrid, Spain

Romanian National Institute of Hematology Transfusion, Bucharest, Romania

State Agency of Medicines of Latvia Riga, Latvia

TRIP (Dutch Biovigilance Agency), Leiden, Netherland