



Co-funded by
the Health Programme
of the European Union



VISTART JA—Newsletter, Issue 1

Grant Agreement 676969

Newsletter, Issue 1
October 2016: first year of activity

About VISTART



Introduction to the Joint Action

VISTART is a Eu co-funded Joint Action (JA), 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.

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Work package (WP) progresses at the end of year 1st:



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Coordination (WPI, led by ISS - CNT//CNS. Italy):

After the kick off meeting held in Luxembourg in October 2015, the JA Management started to monitor the activity of all partners involved in the project and the outputs of the project. The major effort is focused on checking the quality and timing of the activities in order to avoid any gaps between what was planned and the work actually performed.

Next step foresees the technical and financial report to be provided to the CHAFAE as interim deliverable by all the Associated Partners.

Dissemination activities: VISTART and its progresses were presented:

- ⇒ At the Open Day of the Italian National Institute of Health (ISS) in Rome on December 2015
- ⇒ At the 21st PIC/S Expert Circle Meeting on Human Blood, Tissues, Cells & ATPs in Rome on October 2015
- ⇒ At the 17th International Haemovigilance Seminar in Paris on March 2016
- ⇒ At the Meeting of the European Competent Authorities (EU CAs) on Blood and Blood Components in Brussels on April 2016
- ⇒ At the national Congress of the Italian Society of Transfusion Medicine and Immunohaematology (SIMITI) in Bologna on May 2016
- ⇒ At the meeting of the EU CAs for Tissues and Cells in Brussels on December 2015 and June 2016
- ⇒ In the Italian Press release (http://www.quotidianosanita.it/scienza-efarmaci/articolo.php?articolo_id=44068)
- ⇒ In the Official website of CNT (<http://trapianti.net/vistart>) and CNS (<http://www.centronazionalesangue.it/notizie/comunicato-stampa-004>)
- ⇒ In the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells (<http://www.notifylibrary.org>)
- ⇒ In the European editorial on Strengthening Vigilance in the field of Substances of Human Origin across the EU with focus on VISTART published on the Health-EU newsletter n. 181 (http://ec.europa.eu/health/newsletter/181/focus_newsletter_en.htm).





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VÉRELLÁTÓ
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Communication and Public Awareness (WP2, led by HNBTs. Hungary):

This working group is responsible for the dissemination of the initiative with the aim of showing the goals achieved and the different public 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 website (<https://vistart-ja.eu>) was prepared in the beginning of this year. In the private part of the site the consortium partners can follow the project events, communicate among the coworkers and upload or download the different documents. In the published part the visitors can read about the project targets, the WPs and their results that will be published in the different international or national events (meeting, congress, etc.). This year the Layman Brochure was published on paper, too.



Evaluation (WP3, led by RNDVCSH. Romania):

During the first project year this WP consists in the monitoring and feed-back on all performed activities, within the WPs. Their methods are the questionnaires, monitoring the events and evaluate outputs of the project according to the mean targets.



Vigilance reporting for blood, tissues and cells (WP4, led by IPST. Portugal):

The group has worked on harmonising the two existing EU documents on SARE annual reporting (one for blood and one for tissues and cells) for these two sectors – ensuring consistency and information sharing across the fields as required, acknowledging the specificities of the ART sector. The first meeting was an Exploratory Workshop, where existing risk response procedures at national and international levels, and the notification tools used by Member States, both within professional and regulatory networks, have been examined for their strengths and weaknesses. The workshop aimed at establishing the extent to which epidemiological alerts reach stakeholders at the professional level and how this could be improved; the basis for discussions have been a survey developed, circulated and analysed by WP4 on the management at national level of rapid alerts circulated via EU RATC platform. WP has prepared a document about the key good practice principles that emerge during the workshop and should be incorporated in the decision-making and communication procedures at EU level across the sectors of blood, tissues and cells. The group will develop a Guideline on horizon scanning activities to identify new risks, with recommendations for how appropriate preventive measures on an EU-wide basis and across blood, tissues and cells and ART should be developed and communicated at EU and national level, taking into account the variable levels of risk associated with different geographical and epidemiological situations. The first results will be showed during the next Meetings of CAs in Brussels.



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International collaboration for Vigilance Communication and new Preparation Process (WP5 led by ISS – CNT, Italy):

It is divided in two parts:

Part A aims at increasing the participation of EU CAs for blood, tissues and cells in the WHO Notify Project's vigilance didactic tool, the Notify Library of adverse occurrences in transplantation, transfusion and assisted reproduction (www.notifylibrary.org). The concrete result of this collaboration will be the transfer of information from the CA's annual SARE reports as input to the Library's database. The collaboration between EU CAs and the Notify Project built during the VISTART joint action will be sustained in the long term by the mutual benefit achieved. Several steps have been accomplished since the VISTART kick off meeting. A first joint WP4–WP5A meeting was held in Lisbon on April 2016. The Statement of support for the official contribution to the Notify Library, containing a detailed agreement for national vigilance data provision was presented. During the meeting, some partners requested written information regarding the Notify Project. As a result, an invitation letter from the Coordinators, together with a Notify Project's summary was sent to all common WP4 - WP5A partners. In October 2016 the second WP5A meeting was held in Rome, where participants presented examples of didactic cases from their vigilance programmes and exercised in the compilation of the database record template. Currently, the expert group on Notify case identification and submission consists in 15 partners, 9 associated and 6 collaborating (Milestone 10 – Month 3). The first version of the "Guidelines for CAs on how to prepare SARE cases of didactic value for insertion in the Notify library" has been drafted and will soon circulate among the working group members for comments before finalisation (Deliverable 5.1 – Month 15).

Part B intends to develop general principles that should guide CAs of the tissue, cells and blood sectors to evaluate specifically newly developed processing technologies and that should be integrated by clinical follow up information as a mean of further validation of the quality. The EUDTC and EUDB only require that serious adverse reactions/events have to be notified to CAs but to date clinical data submission is not required. The "PRINCIPLES FOR COMPETENT AUTHORITIES FOR THE EVALUATION AND APPROVAL OF CLINICAL FOLLOW UP PROTOCOLS FOR BLOOD, TISSUES AND CELLS PREPARED WITH NEWLY DEVELOPED AND VALIDATED PROCESSING METHODOLOGIES" will represent a first document about the main criteria for assessing clinical outcome of novel products, beside the assessment of quality and safety of new processing methods. Novel technologies or changes of approved preparation processes need to be validated, especially if the processing is at an early stage. The document will describe which are the specific issues to be considered in the risk assessment and risk evaluation of those novelties.



Inspection Guidelines (WP6 led by ANSM, France):

In the first year of the VISTART project the WP6 prepared the guide: The Inspection Guidelines for EU Competent Authorities Responsible for the Inspection of Blood and Tissue Establishments (the Guidelines), set out to meet the objective of the VISTART JA to establish a common framework for the conduction of inspections of blood and tissue establishments across MS through the identification of existing methods, an analysis of comparable approaches and the introduction of complementary procedures. This work has had 2 milestones: the first to design of the survey in collaboration with WP7 to determine the real inspection practice of the CAs in the MS, the second the circulation of the draft inspection guidelines among the CAs for comments. Final Inspection guidelines for EU CAs responsible for the inspection and authorization of blood and tissue and cell establishments will be delivered in January of 2017.



Training of blood, tissues, cells inspectors with sharing of expertise across Member States (WP7 led by ISS – CNS, Italy):

According to the timetable of VISTART, the WP7 started right after the official launch of the Joint Action. Several deliverables and milestones were foreseen in the Grant Agreement and up to now tangible and concrete results were made. In particular, two technical meetings were held in Rome between February and May 2016, and a survey was launched among the EU CAs and some extra-EU CAs, whose main objectives were to identify the criteria and minimum requirements applied at the national level for the recruitment and qualification of inspectors. Its results were elaborated and analysed in a Final Report giving a picture of the current inspection systems in the EU and exploring, through dedicated SWOT analyses, its strengths, weaknesses.



Establishment of a Framework for Joint Inspections (WP8 led by MOH RC, Croatia) and A Voluntary Programme of Inter-Member State Inspection Systems Auditing (WP9 led by HPRA, Ireland):

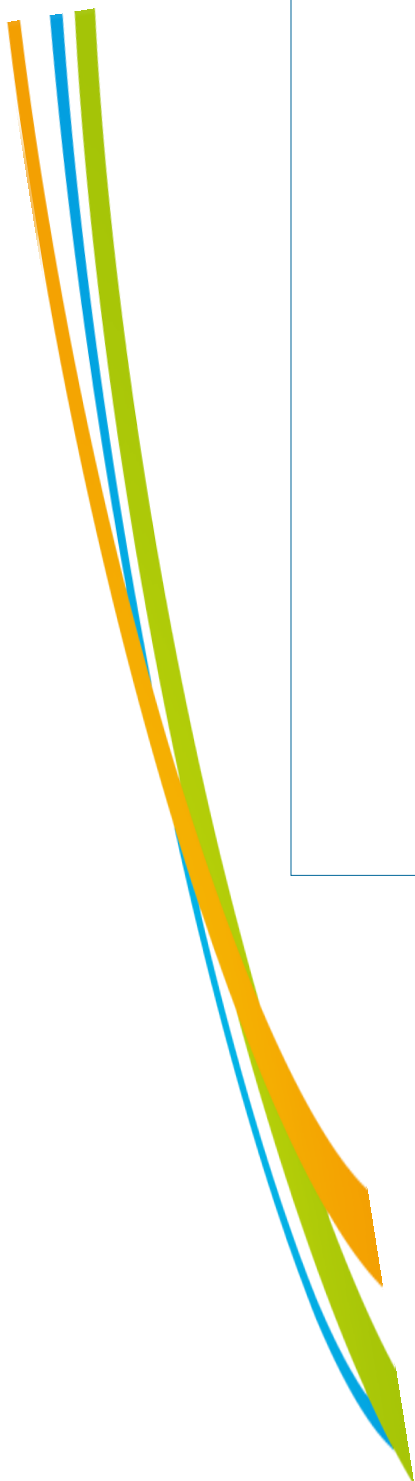
WP8 started with activities in September 2016. According to Grant agreement WP8 first tasks are to organise two plenary workshops back to back to EU Competent Authority (CA) meeting in Brussels and to review and analyse Inspection guidelines, deliverable of WP6 in the beginning of 2017. After WP8 leader identify inspection program with partners, 5 joint inspections are going to be defined, each in a different field of SOHO and in a different Member State. WP8 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 multicountry 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 harmonized inspection bodies' cooperation and support.



WP 9 is led by the Health Products Regulatory Authority (HPRA) in Ireland. This WP has the long-term aim of supporting MS in verifying the equivalence of each other's blood, tissue and cell inspection systems. The key objectives are to build confidence between CAs, thus facilitating blood, tissue and cell distribution between MS; to guarantee citizens who travel across MS an equivalent level of regulation of these services, and to increase the level of quality and safety of substances of human origin used in clinical application through supporting MS inspectorates to achieve continuous improvement and reach equivalent levels of inspection

performance against defined criteria. To support the aims of the WP, the Common European SOHO Inspection Programme (CESIP) will be established by the working group which shall define a process for peer review of blood, tissue and cell Competent Authority Inspectorates and the tools and criteria to be applied as part

of the process. Guidance and documentation for a mutual auditing system by members of one CA or inspectorate of another CA/inspectorate will be developed to assess the level of quality management in place in each CA/inspectorate programme audited. A training programme for auditors shall also be established and a two day training course will be delivered for potential CESIP auditors who will be trained in the appropriate procedures for evaluating the quality and adequacy of the inspection programme in another MS. Participation by MS in the CESIP programme can be foreseen to have a range of benefits: ■ Peer reviewed external validation of the quality systems in place ■ Sharing of expertise and best practice ■ Identifying needs for capacity building ■ Facilitating continuous improvement and institutional change ■ Increasing inter-MS collaboration and confidence in each other's inspections ■ Contributing to greater assurance to patients of receiving safe and effective treatments in the targeted fields, regardless of the MS in which the treatment takes place. This CESIP programme has a view to long-term sustainability with other MS being strongly encouraged to join after the action is closed.





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Poster for the the 32nd Annual Meeting of ESHRE – Helsinki, Finland on July 2016

Implementation of the Single European Coding System in Tissue establishments (WP10 led ISS – CNT, Italy):

WP10 main goal is to provide technical support and guidance to EU Tissue and Cell CAs and to TEs across the EU in the implementation of the Single European Code (SEC) for tissues and cells. In order to successfully reach its goal, the WP10 team set out some tasks to be fulfilled: on site-visits to support the implementation of the SEC, participation to scientific congresses to help professionals through workshops, oral presentations and dissemination of informative material, and an E-Learning course. The team first created a questionnaire, which collected information on where MS were with Coding Directive transposition and then implementation. Nine questions were submitted to all EU Competent Authorities and the answers were collected into a report. Based on the feedback received, the staff did on-site visit in Lithuania who had asked for it, in order to support the correct implementation of the SEC. A four-week E-Learning course was hosted on the CNT platform. It started on September, 5th 2016 and its deadline, which initially was October 3rd, was later postponed to October 17th, allowing users who had so requested, to finalize the course's tasks. Out of 71 users who subscribed to the course, 35 completed it, 22 are still in progress and 14 did not complete it. The WP10 joined two major scientific congresses: the 42nd Annual Meeting of the European Society for Blood and Marrow Transplantation, EBMT - Valencia, Spain on February 2016 and the 32nd Annual Meeting of the European Society of Human Reproduction and Embryology, ESHRE – Helsinki, Finland on July 2016. In these occasions, workshops and oral presentations on WP10 were held, in order to provide professionals with the information they might need to successfully implement the SEC in their countries. In addition, the WP10 staff was available at booths in the exhibition area to clarify any doubt and answer to any question. The WP10 team is now planning to join two more congresses in the next three months: The 25th Congress of the European Association of Tissue Banks, EATB – Hannover, Germany and The XXIX Annual Meeting of the European Eye Bank Association, EEBA – Prague, Czech Republic.



Info Leaflet for the 42nd Annual Meeting of the European EBMT - Valencia, Spain on February 2016



Coordination with other projects or activities at European, National and International level:

Implementation of Single European Code (SEC): the VISTART WP10 offered a number of opportunities to EU T&C TEs and to all the Professionals across EU working in the provision of T&C at human purpose to comply the new EU Directive on SEC to give them an overview of the legal background and the tools that have been developed Implement the legal requirements on SEC in their country.

Notify Library: Taking advantage of the role of CNT as Collaborating Centre of WHO managing the Notify Library (www.notifylibrary.org), VISTART WP5 partA is working to increase the involvement of EU MS CAs in the WHO's Notify Library initiative, where adverse events and reactions of didactic value are evaluated to share the lessons learned as widely as possible, in support of improved safety and quality.

Euro-GTP II: Euro-GTP II (<http://goodtissuepractices.eu/> where CNT is leader of WP5) will determine how TEs and end users must proceed to gather information about safety and efficacy of novel processing methods. On the other hand VISTART (WP5 partB) is working on what is to be assessed by the CAs in order to authorise new T&C&B products, processes and therapies/indications. It will elaborate regulatory principles for CAs for the evaluation and approval of clinical follow up protocols (basic elements) for T&C&B prepared with newly developed and validated processing methodologies, instead Euro-GTP II will propose a tool to identify the risks of new preparation processes and to plan clinical follow up plans proportionate to the degree of risks identified with the tool.

The European Cornea and Cell Transplantation Registry (ECCTR - <http://www.ecctr.org/>) is a European Consortium that aims to build a common assessment methodology and to establish a EU web-based registry and network for academics, health professionals and authorities to assess and verify the safety, quality and efficacy of (new) human tissue transplantations in ophthalmic surgery. The WP5 partB group could appreciate how the ECCTR registry is successful in gathering results about the follow up period. The proposed collaboration between ECCTR and WP5 part B will combine the experience of the clinical registry and the definition of regulatory principles of VISTART on clinical follow up of tissue transplants.

Moreover, this JA will take full advantages of the work and results of previous EU funded projects in the same fields namely: SOHOV&S, CATIE, EuBIS, EUSTITE, EUROCE128, ARTHIQS.



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.K.E.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

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, Zagreb, Croatia

Danish Health and Medicines Authority, Copenhagen, Denmark

EuBIS Academy, 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

Landspítali 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

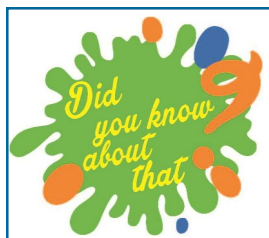
National Centre on Transfusion Haematology, Sofia, Bulgaria

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



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