Summary of context, overal objectives, strategic, relevance and contribution of the action

Seven EU Directives on Blood, Tissues and Cells (B&T&C) were adopted between 2002 and 2006 in order to put in place a Quality and Safety (Q&S) framework for the donation, testing, collection/recovery, processing, storage and distribution of these substances of human origin. In 9 out of 28 Member States (MS) different Entities are responsible for implementing the legislation, whereas in many others this responsibility is incumbent on general health inspectorates, while particularly in smaller MS, the same individuals compile reports or conduct inspections for all of these substances. This scenario is well represented in this Joint Action (JA), where for some countries (i.e. Bulgaria, Croatia, Italy, Poland, Portugal and Romania) both Competent Authorities (CAs) are present as Associated or Collaborating partner and will contribute with their experience to the result of the Action.

Around a decade after the adoption of the Directives, it is apparent that the Q&S principles to protect recipient patients are largely common across these types of donation and that greater consistency and significant efficiency improvements could be achieved by harmonising some of the guidance and tools in use at EU level. This action is evaluating and making proposals for consolidation of some of the key EU tools in place, particularly Inspection guide, training, guidance for annual vigilance reporting and for issuing of rapid alerts.

One of the major objectives of the Directives, that of increasing the possibilities for circulation and sharing of these...
donated substances, has been achieved only to a limited extent, with many MS opting to put in place restrictive import provisions for substances coming from other EU MS. This lack of confidence stems from poorly harmonised implementation and to some extent from a low level of confidence in each other's inspection, authorisation and vigilance systems. This JA is arranging a number of initiatives aimed at increasing the interaction among inspectors from different MS including inspector training, a framework for joint inspections, a pilot for regional inspections by monitoring them that will lead to the creation of an inter-MS inspections system auditing programme. These initiatives will increase harmonisation, promote standardisation to best practice and increase mutual confidence. The impact of these activities will be greatly increased by virtue of their conduct across the fields of B&T&C and Assisted Reproduction. Greater inter-MS circulation of T&C will also be facilitated by this action through support for the harmonised implementation of the Single European Code (SEC) and its associated compendia of tissue establishments (TEs) and tissue and cell products.

Methods and means

This JA is essentially an initiative between EU MS CAs for B&T&C, with a number of key professional organisations contributing. Most of the work is being preformed by Working Groups (WG), who are exploring existing National or EU-wide sector specific programmes and identifying best practice principles for adoption across the Union and by all sectors addressed by the action: blood transfusion, T&C transplantation and Assisted Reproduction. The Consortium is taking full advantage of the work and results of previous EU funded project namely (SOHOV&S, CATIE, EuBIS, EUSTITE, EUROCET128, ARTHIOS), as well as of the results of the Notify Library. The partners are using and/or arranging surveys, exploratory workshops, joint MS inspections, review of existing national or EU documents, meetings with stakeholders and training courses to promote information exchange and develop guidance and training. Each WP leader and implementing technical meetings at their premises or in any other convene place in case of agreed Joint Meeting, but the work is being also conducted by IT-communication, and two general meetings have been already held (kick off, and intermediate plenary meeting) for the general discussion. DG SANTE and CHAFEA have been involved in general and technical meetings according to the representative availability, as well as in the Steering Committee and without the voting rights as foreseen by the new CHAFEA rules. Deliverables, report, guidelines, and any document produced within the Consortium are shared among WP Associated Partners and approved by them.

Work performed during the reporting period

The JA activities started with the kick-off meeting (Milestone - MS.1) held in Luxembourg on October 12th -13th, 2015 at the presence of the CHAFEA and DG SANTE policy officers. Here strong connections among the different WPs were highlighted: VIGILANCE (WP4 and WP5A), and INSPECTIONS (WP6, WP7, WP8, WP9). The Consortium Agreement was signed by all the Associated Partners and the financial guide (MS.25) was sent them at month 6th. During these two years, WP1 - COORDINATION led by CNT-CNS (ISS) was focused on coordinating and supporting the other WP leaders with their meetings and the results obtained and the future steps were shown beforehand to the Coordinator and WP leaders during each meeting of the EU T&C CAs (in particular the last one on February 21st-22nd, 2017), and also Blood and Blood Components CAs meetings (the last one on June 22nd-23rd, 2017). A very fruitful intermediate Plenary Meeting (MS2) was held in Rome on April 11th-12th, 2017 in the presence of almost all the WP leaders and the representatives of the Partecipant Partners. Concerning the WP3- EVALUATION, led by RNDVCSH, the main effort was the drafting of the Monitoring and Evaluation plan and the selection of six international experts from the field B&T&C to build the EAB(D.3.1, MS.27, MS.5). Through an ad-hoc developed online platform (Survey Monkey) and with the support of coordinators and WP leaders providing lists of participants, during this second year all the JA meetings/events were evaluated through self-administered questionnaires, contacts and partners to get their feedback. Concerning the qualitative evaluation of deliverables produced so far, inputs by the EAB members, stakeholders and other experts will be soon incorporated in the Intermediate Evaluation Report (D3.2).

After the first joint meeting with WP5A held in Lisbon in April 2016, IPST for WP4 – VIGILANCE REPORTING FOR BLOOD, TISSUES AND CELLS set up two WGs (MS.28-29), namely: WG1 on Serious adverse Reactions, Serious Adverse Events, Rapid Alert procedures and WG2 on Horizon scanning. Deliverables produced within October 2017 were: D4.1: Unified common approach on SARE reporting for annual reporting to EC and D4.2: Recommendations for harmonization of procedures and platforms for rapid alert for blood, tissues and cells and ART at the EU level. For WP5A - INTERNATIONAL COLLABORATION FOR VIGILANCE COMMUNICATION, CNT delivered the document "Guidelines for CAs on how to prepare SARE forms of didactic value for insertion in the Notify Library" (D5.1) in the beginning of 2017. This document was approved by the CHAFEA and a close connection has been developed between WP5A and the newly formed VIGILANCE Expert Sub-Group rapporteurs for the future vigilance and surveillance activities. The activities of WP5A were showed in many national/international events and the link between the Notify Library and Vistart WP5A was also highlighted by B.I. Whitaker, D.M. Strong, M.J. Gandhi and J. Petrisil in the article "Hemovigilance and the Notify Library" published online in the journal Cell Tissue Banking (2017). https://doi.org/10.1007/s10561-017-9639-0.

For WP5B - PREPARATION PROCESS DEVELOPMENT, also managed by CNT, four meetings were held so far. From the outcome of the survey for collecting information about the existing regulations on approval o

The main output achieved so far and their potential impact and use by target group (including benefits)

In these two activity years the major achieved outputs for:

1) the first objective "To increase consistency and efficiency of competent authority regulatory activities through harmonisation of EU level tools across blood, tissues and cells used in transfusion, transplantation and assisted reproduction": the final version of D4.1 and D4.2 produced. For the guidelines on responding to new risks, WP4 leader will start its work on February 2018 with the Group on the Horizon Scanning. In order to review and analyse the Inspection guidelines of WP6 (in Draft version, MS.13), the WP leader sent them out for comments (deadline December 19th 2016). A final consensus WP6 meeting has been held in Rome on January 19th-20th 2017 to discuss the responses to the consultation and to agree final changes (D.6). These guidelines were approved by the CHAFEA on June 22nd 2017, WP8 leader is using them during its joint inspections (MS.18) started in May 2017; WP2 leader uploaded them on JA website, WP3 leader is evaluating them with the EAB members.

2) the second objective "To increase inter-MS interaction and mutual confidence in their respective inspection and authorisation systems": D7.1 uploaded on the Participant Portal within the deadline. On September 2016, the EC

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• ARTHIQS WP4 CA Workshop October 25th-26th, 2016 Prague (CZ): presentation on "The EU coding system"

• The 32nd Annual Meeting of ESHRE – Helsinki, Finland – 3/7/2016 to 6/7/2016 with Exhibition booth.

The WP10 team together with ICCBA representatives provided professionals with the information they might need to successfully implement the SEC in their countries during:

• By WP10 team

The WP10 team together with ICCBA representatives provided professional support to the SEC during:


Dissemination and evaluation activities carried out so far and their major results

So far the JA was object of presentations given by WP1, WP5A, WP6 and WP10 leader during some International and National Scientific Congresses:

By WP1 team on all WPs (general overview):
• at the Open Day of the Italian National Institute of Health (ISS) in Rome on December 2015.
• at the 31st PIC/S Expert Circle Meeting on Human Blood, Tissues, Cells & ATMPs 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, December 2016 and June 2017.
• at the national Congress of the Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) in Bologna on May 2016.
• at the meeting of the EU T&C CAs in Brussels on December 2015, June 2016, and February 2017.

By WP5A team
• Oral presentation: "NOTIFY roadmap in EU: VISTART Joint Action" at the Second NOTIFY Project Technical meeting, November 28th - 29th, 2016 in Rome (IT).

Oral presentation: "NOTIFY Library of adverse occurrences in transfusion, transplantation and assisted reproduction. VISTART Joint Action" at the 19th National Haemovigilance Meeting, December 12th 2016 in Athens (GR).

• XXIX Annual Meeting Of the European Eye Bank Association, January 19th - 21st 2017 in Prague (CZ).

• XXVII Meeting of the International Expert Group on Blood Bank Quality (IGBQB), 10th 2018; residential module from July 3rd to 6th, 2018 in Rome. Code of practice first draft was produced by WP8 leader in March 2017 before the 1st technical meeting. Comments were collected after the meeting. Last upgrade was made after the joint inspection in Austria on October 2nd - 5 2017.

The identified target groups are institutional stakeholders as well as professionals: European Institution (DG-SANTE, European Parliament, European Council); Council of Europe – EDOM and their working group (CD-P-TO members); World Health Organization (WHO); National CAs and their delegated bodies; Health Ministries; Blood and Tissue Establishments; Transplantation Centres; in-the-field national and international scientific societies; mass media/journalists; general public. While most of the JA results are primarily addressed to CAs for adoption at national level, due attention is being paid also to steady contact with representative of Professional Societies and local level stakeholders. A first identification of res

Achieved outcomes compared to the expected outcomes

The achievement of outcomes is clearly partially pending, since this report is covering the first two years of activity. However in order to prevent the identified external risk that guidelines produced (as objective 1) and other inputs could be agreed but not implemented, training courses and CAs meetings are being used to underline the benefits of harmonized monitoring procedures in order to increase the free circulation of B&TC for the benefits of patients. Concerning the J1 (objective 2), two inspections out of 5 planned have been conducted so far. The WG in charge of define common expectations for patient follow-up protocols (objective 3), as part of process validation, following preparation process changes is trying to guarantee its sustainability involving 10 clinical researchers, experts, and professionals in the field and by proposing to EDOM to include the principles in their two widely used guidance publications on tissue and donor/recipient matching. Consultations with experts and professionals in the field are expected full acceptance by all the CAs. In order to transfer information from EU CA Annual SARE reports as input to WHO Notify Library (objective 4), so far 9 CAs committed to support the Library with their didactic cases, providing the Statement of Support signed to CNT. Further update will be provided in the next technical report. For objective 5’s outcomes, namely the smooth SEC implementation, due as of April 29th 2017, after the period so far covered by VISTART described actions, EUTC TE and Product Compendia were fully updated on Commission website in July 2016.

• Oral presentation: "NOTIFY roadmap in EU: VISTART Joint Action" at the Second NOTIFY Project Technical meeting, November 28th - 29th, 2016 in Rome (IT).

By WP6 team
• Presentation of the project during the 22th expert circle meeting in Hong Kong on November 25th 2016.

By WP10 team
• The WP10 team together with ICCBA representatives provided professional support to the SEC during:


• The 32nd Annual Meeting of ESHRE – Helsinki, Finland – 3/7/2016 to 6/7/2016 with Exhibition booth.

• ARTHIQS WP4 CA Workshop October 25th-26th, 2016 Prague (CZ): presentation on "The EU coding system"

Code for Tissue with Workshop: “Upcoming implementation Single European Code: set-up, next step/timeline, and concrete to do’s for EU tissue establishments”
• The 43rd Annual Meeting of EBMT – Marseille, France – 26/03/2017 to 28/03/2017 booth with dissemination material.

All these occasions were deemed relevant for the purposes of disseminating the contents of the initiative since most of them gathered more than 100

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• LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA
• HELSEDIREKTORATE
Major outputs

No Major output related to the current project