Newsletter Issue 1

January 2019

FacilitatinG the Authorisation of Preparation Process for blood, tissues and cells

GRANT AGREEMENT NUMBER - 785269
May 2018-April 2021

Co-funded by
the Health Programme
of the European Union

About GAPP

GAPP Joint Action (JA) is a 36 month project aiming at facilitating the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments (BEs and TEs), adapting requirements as prescribed by Article 29 of Directive 2002/98/EC and Article 28 of Directive 2004/23/EC. Eighteen (18) European countries are involved with representatives from Competent Authorities (CA) and Scientific Societies aiming to configure European Recommendations for optimal preparation of Blood, Tissues and Cells for therapeutic application. European organisations will also contribute their scientific experience in GAPP.

GAPP Goals: The key objective of the Action is to facilitate the development of a common and optimal approach to assess and authorise preparation processes in BEs and TEs. Particular attention will be devoted to innovative processes under development in the sectors.

Specific objective(s) of the Action: The specific objectives of the GAPP Joint Action can be summarized on the following.

Objectives

01 Achieve a comprehensive review of existing procedures in Member States for Blood, Tissue and Cell preparation process authorisation, identifying strengths and weaknesses and proposing good practices that will be feasible for all Member States to implement.

02 Develop a concept model for a European knowledge-sharing platform that can support CAs in the assessment and evaluation of novel preparation processes of products.

03 Develop an international network of experts trained by the Joint Action that can support CAs in the assessment and evaluation of preparation processes of Blood, Tissues and Cells.

04 Develop a knowledge-sharing platform on preparation processes of Blood, Tissues and Cells to facilitate sharing of information among European Countries. CA inspectors will be trained specifically to assess and authorise preparation processes of tissues, cells, reproductive cells and blood products.

Participants

MAIN PARTNER – COORDINATOR (1)

Istituto Superiore Di Sanita (Italy, project coordinator and WP1 leader)

ASSOCIATED PARTNERS (26):

Papageorgiou General Hospital (Greece, WP2 co-leader); 7th Health Region Crete(Greece, WP2 co-leader); Registrul National Al Donatorilor Voluntari De Celule Stem Hematopoietice (Romania); Ministarstvo Zdravlia Republike Hrvatske (Croatia, WP3 leader); Health and Social Care Inspectorate, IVO (Sweden, WP4 leader); Health Products Regulatory Authority (Ireland, WP5 leader); Organització Catalana de Trasplantaments, OCATT (Spain, WP5 leader); Medicines and Healthcare Products Regulatory Agency (United Kingdom, WP6 group responsible); Agence de la biomédecine (France, WP6 leader and WP7 co-leader); Laakealan Turvallisuus-Ja Kehittamiskeskus (Finland, WP7 co-leader and WP8 co-leader); Bundesinstitut Fur Impfstoffe Und Biomedizinische Arzneimittel (Germany, WP9 leader); Banc De Sang I Teixits (Spain, WP8 co-leader); Krajowe Centrum Bankowania Tkanek I Komorek (Poland, WP10 leader); Human Tissue Authority (United Kingdom); Agentia De Transplant (Republic of Moldova); Executive Agency For Transplantation (Bulgaria); Ministry of Health of the Republic of Cyprus (Cyprus); Medical Products Agency (Sweden); Asociacion Espanola De Bancos De Tejidos (Spain); Servicio Andaluz De Salud (Spain); Hospital of Lithuania University of Health Sciences Kaunas Clinics (Lithuania); Viesoji Istaiga Vilniaus Universiteto Ligonine Santaros Klinikos (Lithuania); Ministry for Health - Government of Malta (Malta); Fondazione Irccs Ca' Granda – Ospedale Maggiore Policlinico (Italy, WP6 group responsible); Ministry of Human Capacities (Hungary)

COLLABORATING PARTNERS (14):

Hellenic National Blood Transfusion Center (Greece); Salar (Sweden); Fundatia Renala (Moldova); Etablissement francais du sang, EFS (France); Agence nationale de sécurité du medicament et des produits de santé, ANSM (France); The State Agency of Medicines of the Republic of Latvia (Latvia); European Society of Human Reproduction and Embryolog (ESHRE); SOHO Consortium; European Centre for Disease Prevention and Control (ECDC) (Sweden); European Hematology Association (EHA); Institute for Transplantation and Biomedicine (Croatia); NHS Blood and Transplant, NHSBT (United Kingdom); Joint Professional Advisory Committee, JPAC (United Kingdom); EDQM (France)

The GAPP JA website

The GAPP EU JA aiming at facilitating the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments has developed its website (www.gapp-ja.eu) to raise awareness about the project goals. With an attractive look, the GAPP JA website is easy and quick to navigate. It presents general information regarding the JA aims, activities, and results, and the different partners of the consortium. All the GAPP JA outputs, as well as the latest activities, news and events are uploaded on the website.

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GAPP faces

Rita PITEIRA
Co-leader of the WP8

Is a Consultant and Project Coordinator for the Banc de Sang i Teixits, which is located in Barcelona, Spain. Rita is a Work Package co-leader for WP8 - Technical Annex 3 to overall guidance: assessing clinical data as part of PPA authorization.

Samuel ARRABAL
Co-leader of the WP7

He works for the Agence de la Biomedicine, which is located in Paris and. He is a co-leader of the WP7 (Technical Annex 2 to overall guidance: assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA)

Gerard SHERIDAN
Co-leader for WP5

Is a GMP Inspector / Blood, Tissues and Organs Manager at Health Products Regulatory Authority of Ireland. George is a Work Package co-leader for WP5 (Development of Overall Guidance on organisation of PPA system)

Paola Di Ciaccio
WP1 - Coordination & Management

Paola is a Project Manager and works for the Istituto Superiore di Sanità | ISS, which is located in Rome, Italy.
ISS is the project leader (WP1) and is responsible to manage and coordinate the project and make sure that it is implemented as planned, following the EC rules and procedures.

GAPP Layman Brochure

The Layman Brochure of the GAPP JA (https://www.gapp-ja.eu/wp-content/uploads/2018/11/GAPP-leaflet.pdf) has been distributed to the partners and stakeholders and has been uploaded in a number of webpages in different countries. We encourage you to circulate it throughout your professional networks. The leaflet contains information about the project's vision as well as a basic summary of the implementation projects and policy dialogues. This leaflet is helpful for both policy-makers and experts to understand the essence of our project and the outcomes we seek to achieve.

GAPP JA Events

Kick-off meeting (June 7-8, 2018): The aim of the meeting was to present the overview of the project to the whole consortium and EC officers and define the preliminary and further actions to be performed by the work packages (WP). The meeting was held in the Instituto Superiore di Sanita, Rome, Italy. A brief description of the WPs is presented here.

Stefaan van der Spiegel (DG SANTE): *"Over the last years, EU MS have done a lot in the framework of other EU funded projects and Actions (VISTART, Euro-GTP II and ECCTR). The aim of this new Action is to build a comprehensive framework for Competent Authorities for a common approach to Preparation Process Authorisation for Blood, Tissues and Cells in the EU and the Commission will support the consortium, to achieve the objectives of the Action".*

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Highlights of the Kick-Off meeting

WP1

Coordination (ISS-CNT-CNS): Paola Di Ciaccio presented the coordination WP. The consortium is composed by 18 European Countries and 40 partners The Action will last 36 months (from May 1st 2018 till April 30th 2021) and EU is contributing for the 80% of the total amount (1.5 M euros).

WP2

Dissemination and communication (PGH and 7 HR Crete, Greece): Eleni Papadaki presented the work of dissemination Work-Package co-lead by the two Greek organisations. The identity of the Action (logo, ppt template, layout for documents) was presented by Lambros Dermetzoglou. The website was showed and it was launched soon after the kick off meeting. In the private area of the website it will be possible to upload all the relevant document, meeting presentations, agenda, minutes. At the end of the Action a multistakeholder conference will be organised back to back to another international conference. EHA conference may be an option.

WP3

Evaluation (MoH HR, Croatia) - Role and nomination of the EAB: The main task of WP 3 is to ensure that the project is being implemented as planned. The work will be carried out in two aspects; internal and external evaluation. Internal evaluation will assess and evaluate all the relevant project's events and outputs through: data recording from routine documentation and pre-release deliverables, surveys, observation, timeline tracking of all projects milestones and deliverables.

WP4

Integration in national policies and sustainability (IVO, Sweden): Mona Hanson presented the content of WP 4. The work of WP 4 will start at M15 with a pilot in Sweden and a report on the implementation will be prepared by M26. IVO will be supported in this activity by the National Council for Organs, Tissues & Cells and Blood.
As far as the implementation in other member states is concerned IVO will prepare a "tool box" containing all the results of WP 5, 6, 7 and 8.

WP5

Development of Overall Guidance on organisation of PPA system (HPRA, Ireland; CatSalut, Spain): Gerard Sheridan and Ruth Barrio presented the content of WP 5. This WP will develop the guidance on organisation of PPA systems defining minimum requirements and guidance for Competent Authorities for the assessment and authorisation of preparation processes for SoHO. WP 5 has a very central role and it will be supported by the preparation of three technical annexes respectively in WP 6, 7 and 8. Strong effort from all associated partners will be asked. The work will start with the revision of existing guidance relevant to PPA procedures including those that were developed by previous projects: EUSTITE, VISTART, Euro-GTP II and ECCTR. For blood and blood components, revision of guidance will be ensured by ad hoc subgroups.

WP6

Technical Annex 1 to overall guidance: authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts): WP 6 is a very technical WP which involves a consistent list of associated and collaborating partners. It covers the overall duration of the action. The work of this WP is divided in two parts: Part 1 will develop definition of the critical characteristics/properties (criteria) for each category of blood component, tissue or cell type (referring to EU blood legislation 2004/33/EU, EDQM) blood component monograph and T&C guide.
Part 2 will develop a Guidance on the assessment of methods to demonstrate achievement/ maintenance of the critical characteristics/properties for each category of SoHO, in particular where changes are proposed/implemented in one of the preparation steps.

WP7

Technical Annex 2 to overall guidance: assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA (ABM, France; FIMEA, Finland): This WP focuses on those technical aspects of processing that aim to reduce the risk of microbial contamination, in particular: donor testing, microbial inactivation during processing, sterilization of final products. The Technical Annex produced by this WP will include an assessment for four kinds of biological products: blood (and blood-derived products), tissues and cells for replacement, haematopoietic stem cells, reproductive tissues and cells. A technical group will define the shape of the document in order to harmonise whenever possible the text. Three Technical Meetings will be organised and the work will be also conducted via teleconferences. Council of Europe is involved in the work of the WP and also ESHRE was invited as collaborating experts.

WP8

Technical Annex 3 to overall guidance: assessing clinical data as part of PPA authorisation (FIMEA, Finland and BST, Spain): WP 8 aims at introducing systematic methodologies for the evaluation of clinical (and technical) data, as part of the authorisation of processing activities. The content of previous project will be taken into account by WP 8. This workpackage aims to achieve common practices and systematic methodologies for the evaluation of clinical (and technical) data as part of the authorisation of processing activities. It was agreed that the first Technical Meeting will be organised jointly with other WPs.

WP9

Knowledge sharing on PPA between EU CAs (PEI, Germany): Dorothea Stahl presented WP9 on behalf of PEI. PEI is responsible for the authorisation of biomedicine, tissue preparation, tissue engineering and transfusion medicine.
The aim of this WP is to lay the grounds for a future implementation of the criteria catalogue resulting from WP 6-8 to allow for a standardised, electronically supported assessment of quality, safety and efficacy of blood, cells and tissues, in the case of state-of-the-art processing procedures as well as in the case of innovative processing procedures.

We strongly encourage anyone to upload the leaflet onto your organisation's website along with the GAPP logo and a link to our Joint Action's website.

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The aim of the meeting was to discuss the work and interconnection among the technical WPs and was held in Agence de la biomédecine premises, in Paris. The following were discussed and decided:

First Technical meeting (September 20-21, 2018)

WP5 will develop a template form for Preparation Process Authorisation (PPA), terms for authorisation, overview of single authorisation steps, organisational model definition of types of authorisations.
The work will start with a desk based reviews of frameworks for medical device, medicines, herbals to ATMP, EMA notes for guidance. Contextually a survey will be circulated among National CAs and a multicountry workshop will be organised.

WP6 is dealing with the definition of key quality and safety criteria. For blood JPAC wrote the red book for authorisation which is very specific for any type of product and will share it with the group.
The aim of WP7 is to prepare the technical Annex 2 devoted to the assessment and authorisation methods related to donor testing, microbial inactivation etc. Annex 2 will contain some remarks on common and distinct criteria regarding the aim of reducing the risk of infectious disease transmission i.e.: 1) Common criteria about donor testing (e.g. HIV 1&2, HTLV 1&2, HBV, HCV, CMV, Syphilis) or emerging threats (Zika, West Nile Virus, etc.); 2) Distinct criteria (e.g. microbial inactivation, sterilisation of final products, the peculiarities of constraints to achieve an adapted environment without compromising the chances of fertilization, embryo development, etc).
Source of information will be: already existing guidelines such as EDQM: Guide to the preparation, use and quality assurance of blood components (vers.19, 2017); Guide to the quality and safety of tissues and cells for human application (vers.3, 2017); European Pharmacopoeia; the quality and safety guidelines of EMA and ICH; results of TRANSPOSE project; ESHRE guideline and good practices; other available national guidelines.

WP8 is to introduce systematic methodologies for the evaluation of clinical data, as part of the authorisation of processing activities. About technical requirements of follow-ups the work plan foresees to use VISTART Principles and EuroGTP II outcome (Good Practices) to determine the minimal requirements for clinical data abiding to VISTART principle and taking advantages of already existing registries, EuroGTP, MS practices and EuroGTP II Survey. Concerning the NCAs assessment procedures of evaluation and authorisation (i.e types of authorisations; how assessment should be performed; documents and inspections required; need for external expertise; technical committees, etc.) WP8 will take advantage of VISTART WP5B survey, GAPP survey, specific Partners' experiences and finally Pharma and 3rd countries scenarios.

Forthcoming Events

GAPP WP6 Expert Workshop, February 11, MHRA, London

The aims of the meeting are the following: (a) To identify the members of the three expert groups (Blood, Tissue and Cells, ART); (b) To identify existing standards and sources of criteria; (c) To extend lists of existing standards and sources of criteria; (d) To define the structure of the technical annex to the deliverable "Good practice guideline to authorisation on preparation processes in blood, tissues and cells" covering the aspects on authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution; (e) To define a plan for the work and allocate the responsibility for the different chapters of technical annex to the experts.

GAPP WP6 Expert Workshop, May 20, London

The main aim of the meeting will be the finalisation of the technical annex before the deadline of the above described deliverable 3

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Recent Events with GAPP visibility

1. CA meeting- Tissues and cells. 20-21 June, 2018, Brussels, Belgium. Organised by the EC.

2. Meeting of the Advisory Committee of the Italian National Blood Center. 27 June, 2018, Rome, Italy.

3. Meeting of the Advisory Committee of the Italian National Blood Center. 19 September, 2018, Rome, Italy.

4. Final Meeting of VISTART JA, 1-2 October, Budapest, Hungary. CNT and OVSZ leader of VISTART dissemination WP.

5. CA meeting- Tissues and cells. 10-11 October, 2018, Brussels, Belgium. Organised by the EC.

6. 10-year Anniversary of National Council for Tissues and Cells (SALAR). 16 October, 2018, Stockholm, Sweden. Organised by the partner Mona Hansson.

7. Dialogue meeting with TE ´s for tissues, cells and ART. 12-13 November, 2018, Stockholm, Sweden. Stockholm, Sweden. Organised by the partner Mona Hansson.

8. Cord Blood Week organized by the Public Umbilical Cord Bank of Crete (partner Eleni Papadaki). 12-16 November, 2018, Heraklion, Crete, Greece.

10. Surveillance of transfusion transmitted infections. 22 December, 2018, Rome, Italy. Organised by the Italian National Blood Center (https://www.centronazionalesangue.it/

11. Conference organised by the Blood, Apheresis and Hemostasis Working Group of the Hellenic Haematology Association. 18-20 January, 2019. Athens, Greece (https://www.eae.gr/images/progr_aimod_aimost_2019_01.pdf)

We wish you a new year filled with wonder, peace, and meaning. Happy 2019!

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