



Newsletter 2

(Jan - Oct 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

Background

Since the directives 2002/98/EC, 2004/23/EC, 2005/61/EC, 2006/86/EC were adopted in Europe, significant technical developments have taken place and the complexity of preparation processes of blood, tissues and cells, has greatly increased.

A variety of process steps has been modified or introduced into routine use and new resulting products are being used in the patients.

Increasing complexity of processing can bring significant quality and functionality improvements of the products for patients' treatment, and/or more efficient use of donations, but it may also bring increased risk, particularly as the level of complexity brings the final product towards the borderline with medicinal products.

The assessment and control of risks should be ensured via the preparation process authorisation procedures in place in each Member State.



Goals

GAPP Joint Action is an ongoing 36 month EU project which addresses the authorisation of preparation processes in blood and tissues and cells aiming at:

Increasing consistency and efficacy of Competent Authority (CA) regulatory activities through harmonisation of EU-level tools for authorisation procedures for preparation processes at Blood and Tissues Establishments, **01**

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

Establishing an international network of specifically trained assessors / inspectors that can support CAs in the assessment and evaluation of preparation processes of products. **03**



Sixteen (16) European countries are involved in GAPP Joint Action with representatives from Competent Authorities, Scientific Societies and Blood, Tissues and Cells Establishments aiming the organization of the evaluation system for therapeutic blood, tissue and cell application practices at the Competent Authorities level. Also, European Organizations contribute their scientific experience.

GAPP consortium so far includes 24 beneficiaries (1 coordinator and 23 associated) and 15 collaborating stakeholders.



2nd Newsletter

In this second edition of the GAPP Newsletter, updates are related to the efforts and progression of Technical WPs in order to enhance and strengthen the knowledge of stakeholders. Three major technical meetings were held during this 9 month period:

- a) the 1st Expert Workshop in London 11th February 2019;**
- b) the 2nd Experts Workshop in Paris May 20th 2019**
- c) the 2nd Joint Technical Meeting of WPs 5, 6, 7, 8 and 9 in Strasbourg, May 21st 2019**

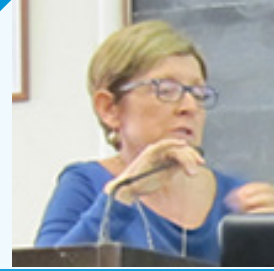
Different deliverables and reports have been produced or drafted which will be discussed in this issue. All participants had a very positive experience in the jointly conception of GAPP's deliverables. So far, GAPP is reaching a wide audience through electronic material, the webpage but also the social media, registering high engagement rates on Facebook and Twitter. There are still 18 months of Project ahead, meaning a lot of goals to accomplish.

GAPP faces



Katia Bruneau

Katia is the new EU project manager at Agence de la biomédecine in charge of piloting GAPP related activities. She specialised in 2014 on EU programmes, funds and EU project management after a more than 10-year experience serving various institutional, private and associative organisations at EU and national level. She managed several international EU projects as well as national projects in the fields of research on education and training and on social and medical-social matters.



Simonetta Pupella

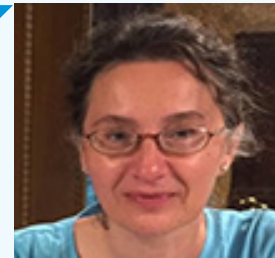
Simonetta is responsible of the Transfusion Safety Area of the Italian National Blood Centre, which is the hub of the National blood system being responsible for coordinating the 21 regional spokes. Dr Pupella has represented Centro Nazionale Sangue (CNS) as associated partner in other EU funded projects and Joint Actions, namely EuBIS, CATIE and TRANSPOSE and co-led the VISTART JA with National Transplant Centre (CNT).

“ The objectives of the Action is to facilitate the development of a common and optimal approach to assess and authorise preparation processes of Blood, Tissues and Cells harmonizing the authorisaion procedures and assuring the safety and effectiveness of related treatments ”



Anu Puomila

Anu has a PhD in genetics. She joined the Finnish Medicines Agency 11 years ago and has worked as Senior Inspector inspecting Blood Establishments, Tissue Establishments and clinical trials. She also works on licenses and SARE/Rapid Alert assessment of Blood and Tissue Establishments.



Vanja Nikolac

Vanja is heading service for blood, tissues and cells from 2009. She participated in numerous activities and projects in SOHO field during the Croatian pre-accession process; worked on harmonisation of SOHO legislation; participated in several EU projects related to the quality and safety of the SOHO and inspection as well.

Events with GAPP visibility

A main dissemination event of the first period of the GAPP project was the presence of the consortium representatives on the 24th congress of the EHA in Amsterdam (June 13-16 2019).

GAPP had a dedicated booth in the Collaboration Plaza of the conference venue, among other European projects, and was supported by representatives of WP2, CNT and CNS who had the opportunity to communicate the expected outcomes and the up-to-date achievements of the Joint Action to the 12.000 attendees of this highly important conference and disseminate the project material (JA Layman brochure, 1st Newsletter etc).



RECENT PER AREA

WP1

GAPP CONSORTIUM COORDINATION

WP Leader: Istituto Superiore di Sanità (ISS – CNT – CNS), Italy

The major effort of GAPP WP Management was 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. From an administrative point of view the Joint Action is facing some changes in the composition of the consortium due to the withdrawal of two Swedish organisation (IVO and MPA). This required WP1 to reallocate workloads and funding within the consortium and the amendment procedure to the grant agreement was launched. WP4 was assigned to the Romanian National Registry of Hematopoietic Stem Cells Voluntary Donors (RNDVCSH), and to ISS-CNT-CNS as co-leader.

In this Joint Action, WP1 is also receiving much support from collaborating beneficiaries not only from a scientific point of view, thanks to the effort they put in the work of technical WPs, but also in the organisation of meetings (the second joint technical meeting was held in Strasbourg at the premises of the Council of Europe, with the support of EDQM) and from a dissemination point of view with reference to the possibility given by the European Hematology Association (EHA) to participate, attend and disseminate GAPP activities in the premier hematology international conference in Europe with thousands of participants coming from all over the world. Notably, EHA is a collaborating partner of GAPP Joint Action

WP2

DISSEMINATION

WP Co-Leaders: PGH + HRC, Greece

The objective of the dissemination and communication WP is to raise the awareness about the activities and outcomes of the Joint Action GAPP and the developments that have been achieved. WP2 promotes the activities of GAPP using the stakeholder lists and number of communication tools such as the website (www.gapp-ja.eu) and the social media as wells as through the preparation and dissemination of the present Newsletter in collaboration with all WP beneficiaries. Moreover, the private part of the GAPP website is being regularly refreshed by WP2 (work documents, deliverables, minutes etc.) to facilitate the internal communication among GAPP beneficiaries .

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A GAPP dedicated booth in the Collaboration Plaza of the conference venue, among other European projects, was supportedby representatives of WP2, CNT and CNS who had the opportunity to communicate the goals and achievements of the Action and disseminate the related material (JA Layman brochure, 1st Newsletter etc) in more than 12.000 attendees of this high visibility conference.

RECENT PER AREA

WP2

The key performance indicators for the evaluation of the effectiveness of the dissemination tools are systematically evaluated internally in WP2 and WP2 beneficiaries have initiated the interim evaluation of Dissemination Strategy according to a main Milestone of the WP.

WP3

EVALUATION

WP Leader: MoH HR, Croatia

The main goal of WP3 is to ensure that the project is being implemented as planned, reaches its objectives and produces high quality deliverables. In accordance with the specific objectives of the project, the External Advisory Board composed by recognized experts has been established and has provided expertise in the evaluation of specific scientific and/or expert issues of project events and outputs. One deliverable (D3.1 - Final Evaluation Plan) has been produced. This document sets out an evaluation methodology to be implemented during the GAPP Joint Action lifetime, starting May 2018.

External advisory board		Info
BLOOD	Johanna C. Wiersum-Osselton, MD, PhD	1) Sanquin Blood Bank 2) TRIP National hemovigilance and biovigilance office , Leiden, The Netherlands
TISSUES	Prof. Johan Guns, MSc.	UZ Brussel (University Hospital Vrije Universiteit Brussel-VUB) , Brussels, Belgium
HSC	Ineke Slaper Cortenbach, PhD	Slaper-Cortenbach, biomedical consultancy , De Bilt, Netherlands
MAR	Kelly Tilleman, MD, PhD	Ghent University Hospital , Ghent, Belgium
TTD testing	Ines Ushiro Lumb, MD, MSc, FRCPath	1) National Health Service Blood and Transplant 2) Public Health England , London, UK
MICROBIOLOGY	Veroniek Saegeman, MD, PhD	1) AZ Nikolaas , Sint-Niklaas 2) UZ Leuven , Leuven, Belgium
CLINICAL TRIALS	Andrijana Tivadar, MPharm, PhD	Slovensko farmacevtsko društvo (SFD) - Slovenian Pharmaceutical Society , Ljubljana, Slovenia

Five GAPP events were evaluated and analyzed, one deliverable was evaluated with the contribution of External Advisory Board. More than 15 surveys have been made and distributed via SurveyMonkey among the project collaborating and associated beneficiaries with the aim of assuring the highest possible quality of GAPP JA implementation.

WP4

INTEGRATION IN NATIONAL POLICIES AND SUSTAINABILITY

WP Coleaders: RNDVCSH, Romania and ISS-CNT-CNS, Italy

This WP aims to set up a plan to describe the potential of GAPP results for integration in policies (at national, regional or local levels) and to ensure the sustainability of the JA activities at national or on the local or regional level.

WP4

As a final result a common proposal for supporting a sustainable implementation in single countries will be agreed upon. The work of WP4 has already started at M15 and a report on the implementation will be prepared by M26. Following the withdrawn of IVO, Sweden, WP4 is now coordinated by the Romanian National Registry of Hematopoietic Stem Cells Voluntary Donors (RNDVCSH) and ISS-CNT-CNS.

WP5**DEVELOPMENT OF OVERALL GUIDANCE ON ORGANIZATION OF PPA SYSTEM**

WP Leader: HPRA, Ireland; OCATT, Spain

WP5 of the GAPP JA will develop guidance on how a preparation process authorisation (PPA) system should or could be organised. A WP5 workshop was organised on October 23. The purpose of this Multi Country Workshop (MCW) to promote discussion to consider and gather information on the status of Preparation Process Authorisation (PPA) systems, the associated legislative requirements, guidance and procedures in place across MS CA's in the field of tissues and cells and Assisted Reproductive Technology (ART).

The main topics that will be analysed during the MCW are:

- a) Framework for Competent Authority;
- b) Application process;
- c) Risk Assessment;
- d) Review and Evaluation;
- e) Authorisation.

The workshop will take place at the premises of the European Commission, Albert Borchette Conference Centre on October 23rd from 14:00 to 18:00.

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 Leader: ABM, France

WP6 is dealing with the definition of key quality and safety criteria of the preparation of blood, tissues and cells that will be used in patients and consist the basis for the authorization. To define these criteria, three specific subgroups of experts were generated. The (MHRA) (UK) led the work on Blood, The Cell Factory - Unit of Cell Therapy and Cryobiology, Fondazione IRCC Ca' Granda Ospedale Maggiore Policlinico, Milan led the work on replacement tissues & cells, and the ABM (France) led the work on Reproductive tissues & cells.

The blood group organized a survey to collect national available procedures and analyse current practices. They could gather more than 40 existing criteria and 3 evaluation tables, and suggested a 14 steps evaluation route for novel components. The ART group decided to include all Medically assisted reproduction activities (MAR) in order to align with EHSRE recommendations and with the EDQM guides. They listed criteria for biological processes used in the different preparation steps and specified their key performance indicators that need to be assessed in the evaluation procedure. The group for Tissues and Cells splitted the work according to the different type of products. Now there are two different groups: the group Cells is leaded by EBMT/JACIE and the group Tissues is leaded by ABM.

WP6

Tissue type categories were defined and the group could share the high workload between its members to design exhaustive tables of criteria. The next steps will consist of circulating the first findings to new experts during a consolidation phase and then, the four subgroups will start working on a guidance to assess the methods demonstrating that criteria/critical characteristics/properties for each category of SoHO have been achieved, especially when changes occur in one of the preparation steps.

WP7

TECHNICAL ANNEX 2 TO OVERALL GUIDANCE: ASSESSING THE QUALITY AND SAFETY OF DONOR TESTING, PATHOGEN REDUCTION AND STERILISATION STEPS AS PART OF PPA

WP Leader: ABM, France; FIMEA, Finland

This WP focuses on those technical aspects of processing that aim to reduce the risk of infectious disease transmission, in particular donor testing, pathogen reduction during processing and sterilization of final products. The beneficiaries of this WP have achieved the milestone to agree on a plan of the Deliverable “Technical annex to overall guidance on assessing the quality and safety of donor/donation testing, pathogen reduction and sterilization steps as part of PPA”. The Deliverable has been structured into 5 chapters as follows:

- Requirements for selection, validation and performance of donor / donation infectious marker screening kits, assays and other methods
- Requirements and criteria for laboratories performing donor and blood component/tissue/cell graft testing
- Criteria for validation of pathogen reduction steps
- Criteria for validation of sterilization processes
- Requirements and criteria for microbiological quality of the final product

Each chapter has been addressed by a specific subgroup composed of beneficiaries, collaborating organizations and invited experts. The 5 subgroups defined the general methodological approach and have started drafting the content of the final document.

WP8

TECHNICAL ANNEX 3 TO OVERALL GUIDANCE: ASSESSING CLINICAL DATA AS PART OF PPA AUTHORISATION

WP Leader: Finnish Medicines Agency (FIMEA; Finland), Barcelona Tissue Bank (Spain)

This WP is aiming to introduce systematic methodologies for the evaluation of clinical data as part of the authorization of processing activities.

WP8

A main Deliverable of the WP is a Catalogue of existing clinical data appropriate to provide information on the quality and safety of human blood, cell, and tissue therapeutics once applied to patients, under the conditions of current state-of-the-art processing and testing protocols. The Deliverable has been finalized.

Another Deliverable of this WP is a catalogue of risk-based set of criteria, appropriate to evaluate the established catalogue of clinical data for completeness and suitability in case of introduction of innovation to the current processing and testing protocols for human blood, cell, and tissue therapeutics. This Deliverable is currently being drafted by the WP8 leaders. Finally, the structure of a third Deliverable of this WP has been drafted and two subgroups of invited experts and collaborating beneficiaries will start working on that. This Deliverable concerns methodological framework to evaluate quality and safety of human blood, cell, and tissue therapeutics based on clinical outcome data requested for authorisation processes upon introduction of innovation to the current processing and testing protocols for human blood, cell, and tissue therapeutics.

WP9

KNOWLEDGE SHARING ON PPA BETWEEN EU CAS

WP Leader: PEI, Germany

Started in May 2019, the WP9 aims at laying the grounds for a future implementation of the criteria catalogues resulting from WP6 WP7 and WP8, thus allowing 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. A platform will be generated that will contain all the relevant information like a kind of guidance.

It will include knowledge sharing content including a teaching part and an access to Member State assessments.

WP10

TRAINING COURSES AND MANUAL FOR TRAINING

WP Leader: KCBTiK/NCTCB, Poland

The work of WP10 is strictly connected to the final results of the WP5, WP6, WP7, WP8 and WP9. On the basis of agreed documents: "Overall Guidance on organization of PPA system" and technical annexes, this WP will organise training courses and prepare "Manual for training CA inspectors that assess and authorize preparation processes of tissue, cell, and blood products", to disseminate the approach throughout Member States.



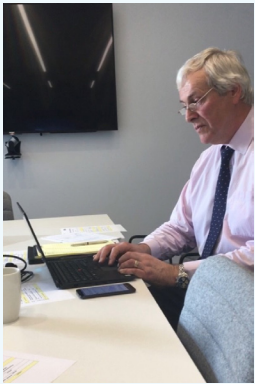
Expert Workshops are directly related to the core business of the project and willing to provide assistance in the Technical Annexes preparation.

Expert Workshops

London (11/02/2019)

Paris (20/05/2019)

organized by GAPP WP6



Two workshops of Experts in Blood, Tissues and Cells and MAR were organized by beneficiaries of WP6 aiming to support the preparation of the Deliverable of the Action “Technical Annex on authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution”.

The first meeting was hosted by MHRA, UK in London and the second by ABM, France in Paris. The specific aims of the Workshops were the identification of existing and extension of standards and sources of criteria of the processes consisting the Deliverable and distribution of the draft in external groups of Experts.

GAPP Consortium Experts, Associate beneficiaries, Collaborating stakeholders and EC Officers participated in the Workshops advancing further not only the preparation of the Annex but also science in the field of blood, tissues/cells and MAR through fruitful discussions.



Forthcoming Events

GAPP Intermediate Meeting October 29-30, Rome

GAPP Intermediate Meeting will be held in Rome from 29th to 30th of October 2019.

WP6 GAPP Technical Meeting October 30, Rome

GAPP WP6 technical meeting will be held in Rome right after the Intermediate meeting

Working Group on Safety of Donated Blood, November 4, Helsinki, Finland


Finnish Medicines Agency

National Tissue Establishment Day, November 21, Helsinki, Finland

Finnish Medicines Agency on National Tissue Establishment Day



Recent Events with GAPP visibility

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1. Advisory Committee Meeting, Italian National Transplant Centre, Rome, Italy, February 11, 2019.
 2. Registry Meeting, Italian National Transplant Centre, Brussels, Belgium, February 20, 2019
 3. Blood Donor Health and Safety Conference, Italian National Transplant Centre, Rome, Italy, March 28, 2019
 4. 11th Panhellenic Congress of Hellenic Blood Transfusion Society, Athens, Greece, April 5-7, 2019
 5. Global Product Safety Conference, Italian National Transplant Centre, Rome, Italy, April 10, 2019
 6. Meeting of the Competent Authorities for Tissues and Cells, EC, Brussels, May 13-14, 2019
 7. The Third Congress of the Romanian Society of Bone Marrow Transplantation, Bucharest, Romania. May, 9-11, 2019
 8. European Hematology Association Conference, Amsterdam, The Netherlands, June 13-16, 2019.
 9. Meeting of the Competent Authorities for Blood, EC, Brussels, Belgium, June 19-20, 2019
 10. Conference organised by the Transplant Agency and Association of Transplant Beneficiaries of the Republic of Moldova, Chisinau, Moldova, June, 2019
 11. 1st meeting of Nordic Council of Ministers Working Group on Blood, Tissues and Cells, Nordic Council of Ministers Working Group on Blood, Tissues and Cells, Copenhagen, Denmark, September 10 2019
 12. Meeting of the Competent Authorities for Tissues and Cells, EC, Brussels, October 22-23, 2019

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GAPP PROJECT

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