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About GAPP

> DEVELOPING A COMMON AND OPTIMAL APPROACH TO ASSESS AND AUTHORIZE PREPARATION PROCESSES IN BLOOD AND TISSUES ESTABLISHMENTS

GAPP Joint Action is aiming at facilitating the development of a common and optimal approach to assess and to authorise preparation processes in Blood and Tissues Establishments throughout Europe. GAPP will contribute to the harmonisation of procedures related to Blood, Tissue and Cell therapies among Member States ensuring the safety and effectiveness of these treatments.

Adoption of the specific EU regulations such as Article 29 of Directive 2002/98/EC and Article 28 of Directive 2004/23/ EC, is a prerequisite for the harmonisation of the authorisation of the preparation processes of Blood, Tissues and Cells. Building on the existing legislation and experience of the Member States adapted in the technical and scientific progress and innovation, GAPP will develop a common approach for tackling authorisations in Blood and Tissues Establishment.

Particular attention will be devoted to innovative processes under development and/or previously described in the reports of relevant EU Joint Actions. GAPP will not only ensure that benefits of these improved technologies will be available to patients via robust authorisation procedures in Blood and Tissue Establishments, but contribute to greater assurance of safe and effective Blood transfusion, transplantation of Tissues and Cells and Assisted Reproduction.

Preparation processes in Blood and Tissue Establishments will be shared among GAPP partners and finally among Member States through the development of a common knowledge-sharing platform. Competent Authorities' inspectors will be trained by means of specific Courses and Guidelines dedicated to assessment and authorisation of preparation processes of Tissues, Cells, and Blood products.

Partners

MAIN PARTNER – COORDINATOR (1)

Italian National Institute of Health, National Transplant Centre, National Blood Centre (Italy, project coordinator and WP1 leader)

ASSOCIATED PARTNERS (25)

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 (Sweden, WP4 leader); Health Products Regulatory Authority (Ireland, WP5 co-leader); Servei Catala de la Salut (Spain, WP5 co-leader); Medicines and Healthcare Products Regulatory Agency (United Kingdom, WP6 blood 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 tissues and cells 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); ESHRE; SOHO Consortium; ECDC (Sweden); European Hematology Association; Institute for Transplantation and Biomedicine (Croatia); NHS Blood and Transplant, NHSBT (United Kingdom); Joint Professional Advisory Committee, Joint Professional Advisory Committee (United Kingdom); Council of Europe, European Directorate for the Quality of Medicine and Health Care (France).

GAPP PROJECT

GRANT AGREEMENT NUMBER - 785269
May 2018-April 2021

Web: www.gapp-ja.eu
Email: info@ gapp-ja.eu

GAPPjointAction || GAPPja

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

GAPP Objectives

To facilitate the development of common and optimal approaches to assess and authorise preparation processes in Blood and Tissue Establishments taking into consideration innovative procedures and technologies.

To increase consistency and efficacy of Competent Authorities regulatory activities through harmonisation of EU-level tools for authorisation procedures of preparation processes at Blood and Tissue Establishments.

To develop a concept model for a European knowledge-sharing platform that can support Competent Authorities in the assessment and evaluation of novel preparation processes of Blood products, Tissues and Cells.

To train an international network of experts capable of supporting the Competent Authorities in the assessment and evaluation of preparation processes of Blood products, Tissues and Cells.

Expected outcomes

Three important tools will be developed for the facilitation of the Competent Authorities to harmonise the regulatory activities concerning Blood, Tissue and Cells among Member States.

- Guidance on organisation of Preparation Process Authorisation system including three Technical annexes (key quality criteria on Blood, Tissues, Cells; quality and safety of processing; assessment of clinical data);
- A knowledge sharing platform on Preparation Process Authorisation;
- A tested training program for inspectors.

Horizontal Workpackages

WP1

COORDINATION OF THE ACTION
WP leader
Italian National Institute of Health &
National Transplant Centre &
National Blood Centre, Italy

WP2

DISSEMINATION & COMMUNICATION
WP leaders
Papageorgiou General Hospital Thessaloniki &
7th Health Region Crete, Greece

WP3

EVALUATION
WP leader
Ministry of Health, Republic of Croatia

WP4

INTEGRATION IN NATIONAL POLICIES & SUSTAINABILITY
WP leader
The Health and Social Care Inspectorate, Sweden

Technical Work Packages

WP5

Development of Overall Guidance on organization of Preparation Process Authorisation (PPA) system

WP leaders: Health Products Regulatory Authority, Ireland & Servei Catala de la Salut, Spain

Starting with the review of the existing guidance relevant to preparation process authorisation procedures including those that were developed by previous EU funded projects (EUSTITE, VISTART, EUROTGPII, ECCTR), WP5 will perform surveys and evaluation of the Preparation Process Authorisation procedures in force in the various Member States with the final aim to develop a best practice guideline on how the PPA program should or could be organised.

WP6

Tecnical Annex I on authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package)

WP leader: Agence de la biomédecine, France

The first technical annex will define clear quality criteria for different Blood components and Tissue and Cell types to facilitate PPA steps and ensure patients' outcome. The WP will be divided in two parts: the first part will involve the definition of key quality and safety criteria for each category of Blood components, Tissues or Cells giving attention to the criteria that need to be validated or verified through in vitro or clinical studies. The second part will develop guidance on how to ensure these criteria are met through in vitro validation, in-process verifications or clinical studies.

WP7

Technical Annex II on assessing the quality and safety of donor testing, microbial inactivation and sterilization steps as part of Preparation Process Authorization

WP leaders: Agence de la biomédecine, France & Laakealan Turv Allisuus-ja Kehittamiskeskus, Finland

Technical Annex II will focus on those technical aspects of processing that aim to reduce the risk of infectious disease transmission, in particular donor testing, microbial inactivation during processing and sterilisation of final products. The biological quality and safety parameters of Blood, Tissues and Cells and Reproductive Tissues and Cells will be defined for each step, from donation to the application on recipients.

WP8

Technical Annex III on assessing clinical data as part of Preparation Process Authorisation

WP leaders: Laakealan Turv Allisuus-ja Kehittamiskeskus, Finland & Banc de sang i teixits, Spain

This WP aims at defining the current state of the art of existing clinical data appropriate to provide information on the quality and safety of human Blood, Cell, and Tissue therapeutics once applied to patients; defining a risk-based framework to assess whether the current state-of-the-art criteria fit to new processing or testing protocols; defining a methodological framework to evaluate quality and safety based on clinical outcome data requested for authorisation processes upon introduction of innovation to the current processing and testing protocols; building a data model information on clinical outcome of application of human Blood, Cell, and Tissue therapeutics, building also bridges to existing clinical databases such as ECCTR, EBMT, EuroGTPs, registries.

WP9

Knowledge sharing on Preparation Process Authorisation between EU Competent Authorities

WP leader: Bundesinstitut fur Impfstoffe und Biomedizinische Arzneimittel, Germany

This WP aims at implementing the criteria catalogues resulting from WP 6-8 to allow for a standardised, electronically supported assessment of quality, safety and efficacy of Blood, Cells and Tissues in both, state-of-the-art and innovative processing procedures. The work will be performed in three blocks: building on the data models set up in WP 6-8 to generate a structure that will display the dependencies of preparation and testing methods with clinical outcomes; building the framework for an electronically supported authorisation process based on the integrated data model; development of the concept of a platform to implement obtained data.

WP10

Training Courses

WP leader: Krajowe Centrum Bankowania Tkanek i Komorek, Poland

This WP will organise training courses and will finally prepare a "Manual for training Competent Authorities' inspectors that assess and authorise preparation processes of Tissue, Cell, and Blood products". This approach will be disseminated throughout EU Member States, Serbia and Moldova and made available to train national or regional inspectors in the future.

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