

About GAPP



“

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

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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 Zdravlja 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); Paul Erlich Institute (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 médicament 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

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FACILITATING THE AUTHORISATION OF PREPARATION PROCESS FOR BLOOD, TISSUES AND CELLS



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