GAPP PRO

Co-funded by the European Union

Piloting GAPP model approach for assessing and authorizing novel substances of human origin preparation PROcess

Overview

The GAPP-PRO Joint Action (JA) stands as proceedings of the previous European initiative GAPP and brings together national Competent Authorities (CAs) and other stakeholders involved in the field of preparation process authorization.

In the last years, a significant progress has been made impacting the field of Substance of Human Origin (SoHO): new methods of testing for viruses to ensure safe donations, new scientific evidence on donor selection/deferral criteria, new genetic testing for extensive screening of gamete donors; innovative methods of processing blood, tissues and cells (e.g. pathogen reduction strategies); new categories of patients/donors due to new clinical practices. Moreover, the epidemiological situation has changed worldwide given to the increased global circulation of citizens favouring the spread of viruses.

In this context, the rapid growth of innovative therapies based on SoHO involves several medical and surgical fields, dealing with increasing therapeutic opportunities for patients in Europe. The several applications of platelet components, mainly in the autologous and bedside setting (e.g. platelet concentrated, lysate), as well as cellular components (adipose tissue, bone-marrow-derived cells, decellularised cardiac tissue, skin tissue and combined use of tissues with medical devices) and other SoHO as faecal microbiota, represent an example of a quite spread SoHO therapy, thanks to the continuous development of new medical devices. Additionally, some SoHO preparations already authorised by CAs are used for different clinical indications, without a specific risk analysis.

The lack of standard specifications of the products/preparation processes and the lack of a common approach for the authorisation procedures may have an impact on the quality, safety and accessibility of the therapies for patients. Hence, there is a high need to promote harmonisation of the authorisation procedures and of the evaluation risk, which are still very different among Member States (MSs).

Objectives

The JA aims at testing and perfecting GAPP JA (GA 785269) methodology, through the following actions, whilst ensuring EU wide adoptions of guidelines, findings and JA legacy:

- piloting of **authorization processes** for different substances of human origin (eg: faecal microbiota, breast milk, platelet lysate eye drops), including bedside preparations;
- **verifying the capability** to implement the GAPP model in the different MSs, with special reference to a common assessment of risk levels;
- **testing the methodology** in a perspective of multi-country assessment;
- **testing the feasibility** of joint assessments, including – whenever necessary – interactions with stakeholders from the fields of medical devices and pharmaceutical;
- **updating the EuroGTP II** risk assessment tool extending the already available platform to other SoHOs (namely fecal microbiota and breast milk);
- **refining the Good Practice Guideline** to authorization on preparation process in blood, tissues and cells establishments, developed in previous GAPP JA, taking advantage of the results of the pilot tests as well as the opinions of the different professionals and competent authorities that took part in the pilot tests.

Consortium

14 main beneficiaries + 7 Affiliated entities from 13 EU countries and 1 non-EU country

Project duration

40 months, February 2024 – June 2027

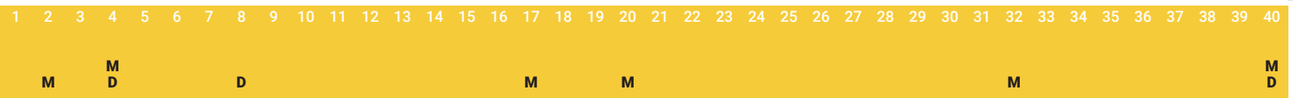
Estimated cost

€ **1.874.996,31** with an EU contribution of € 1.499.997,06

WP1. Coordination and Sustainability

ISS/CNT-CNS

WP1 is aimed to manage and coordinate the JA activities and make sure it is implemented as planned, following EC rules and procedures. Additionally, WP1 will explore the possibility to make the results sustainable and tangible.



WP2. Dissemination and Communication

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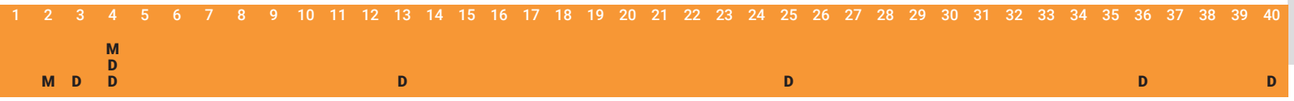
The overall objective of the WP is to identify and reach the target audience and stakeholders, including EU and national policy makers, professional associations and societies, end users and the general public, in order to raise their awareness regarding the findings of the consortium.



WP3. Evaluation

PUMS

The main goals are to both attain objectives and assess effectiveness of the JA. Specifically, this WP will monitor that the JA is implemented as planned, in terms of tasks, milestones and deliverables; evaluate the JA activities in terms of process adherence, output, outcome and impact based on an evaluation.

WP4. Snapshot of SOHO preparation processes

SZU, PUMS

The successful implementation of WP4 is extremely important considering that it lays down the foundation for activities of the other technical WPs. The main goal is to gain clear insight into the current European authorisation of SoHO preparation processes, including bed-side preparations, grouped by different risk level.

1–40 = Project duration (months) | **M** = Milestone | **D** = Deliverable

WP5. Pilot-test of GAPP methodology on SoHO

ABM

The goal is to assess the GAPP methodology applicability on selected SoHO, from application to final assessment. The assessment will be performed through the organisation of pilot-tests involving a Working Group of experts coming from BTC establishments, scientific societies and professional/CAs assessors representing at least 5 countries.

WP6. Pilot-test of GAPP methodology for cross country and joint country assessments

ABM, AGES

WP6 represents the core WP of the JA being strictly correlated to the other technical WPs. One of the pivotal objectives of the WP6 is to organise and perform cross-country and joint-cross country assessments. This activity will benefit from the involvement and collaboration of CAs and groups of experts selected by the competent authorities involved in the action and in the specific WP.

WP7. Analysis of pilot tests results

OCATT

The main objective of WP7 is to perform a thorough analysis of the pilot outcomes developed by WP5 and WP6. Within this context, interactions with stakeholders from other frameworks will be taken into due consideration. For example, where a new SOHO preparation process relies on the use of a new medical device.

WP8. Refine of GAPP guideline

ISS/CNT-CNS, OCATT

The main goals are to extend the EuroGTP II risk assessment tool to other SoHOs (namely fecal microbiota and breast milk) and refine the GAPP Guideline to authorisation on preparation process in blood, tissues and cells, taking advantage of the results of the pilot tests as well as the opinions of the different professionals and competent authorities that have taken part in the WP5 and 6 pilot tests.

Scan the QRcode and visit the project website: **https://gapp-pro.eu/**.

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BENEFICIARIES

ISS/CNT-CNS, Istituto Superiore Di Sanità, Centro Nazionale Trapianti, Centro Nazionale Sangue, Italy | **AGES**, Osterreichische Agentur Fur Gesundheit Und Ernahrungssicherheit Gmbh, Austria | **MOH HR**, Ministarstvo Zdravstva Republike Hrvatske, Croatia | **MPHS**, Ministry Of Health Of The Republic Of Cyprus, Cyprus | **STPS**, Styrelsen For Patientsikkerhed, Denmark | **ABM**, Agence De La Biomedecine, France | **HTO**, Hellenic Transplant Organization, Greece | **NNGYK**, Nemzeti Nepegeszsegugyi Es Gyogyszereszeti Kozpont, Hungary | **HPRA**, Health Products Regulatory Authority, Ireland | **TRIP**, Stichting Trip Transfusie En Transplantatiesreacties In Patienten, Netherlands | **PUMS**, Uniwersytet Medyczny Im Karola Marcinkowskiego W Poznaniu, Poland | **SZU**, Slovenska Zdravotnicka Univerzita V Bratislave, Slovakia | **OCATT**, Servei Catala De La Salut, Spain | **UTCC**, Specialized State Institution “Ukrainian Transplant Coordination Center”, Ukraine

AFFILIATED ENTITIES

ANSM, Agence Nationale De Securite Du Medicament Et Des Produits De Sante, France | **OVSZ**, Orszagos Verellato Szolgalat, Hungary | **DPC**, Del-Pesti Centrumkorhaz-Orszagos Hematologiai Es Infektologiai Intezet, Hungary | **BST**, Banc De Sang I Teixits, Spain | **ONT**, Organizacion Nacional De Trasplantes, Spain | **MOH ES**, Ministerio De Sanidad, Spain | **TICSALUT**, Fundacio Ticsalut, Spain

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