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# GAPP-PRO D2.1

## Dissemination and Communication Plan

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## List of abbreviations

AEs	Affiliated Entities
ALAN	Acute Leukaemia Advocates Network
BEN	Beneficiary/ies
BTC	Blood, Tissue and Cells
CAs	Competent Authorities
CCI Europe	Childhood Cancer International Europe
CLLAN	Chronic Lymphocytic Leukaemia Advocates Network
CML	Chronic Myeloid Leukemia
HaDEA	European Health and Digital Executive Agency
DCP	Dissemination and Communication Plan
EAHP	European Association of Hospital Pharmacists
EATCB	European Association of Tissue and Cell Banks
EBA	European Blood Association
EBTM	European Society for Blood and Marrow Transplantation
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines
EEBA	European Eye Bank Association
EFAPH	European Federation of Associations of Patients with Haemochromatosis
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHC	European Haemophilia Consortium
EMA	European Medicine Association
EMBA	European Milk Bank Association
EPF	European Patient Forum
ESCF	European Sickle Cell Federation
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
EuroGTP	European Good Tissue & Cell Practices

EURORDIS	Rare Diseases Europe
FIODS / IFBDO	International Federation of Blood Donor Organizations
GAPP	facilitatinG the Authorization of Preparation Processes for blood, tissues and cells
IBMT	Indiana Blood and Marrow Transplantation
ISBT	International Society of Blood Transfusion
ITP	Immune thrombocytopenia
JA	Joint Action
LC	Lymphoma Coalition
MAR	Medically Assisted Reproduction
MDS	Myelodysplastic Syndromes
MPE	Myeloma Patients Europe
MPN AN	Myeloproliferative neoplasms Advocates Network
MS	Member State
NGOs	Non-Governmental Organizations
OECD	Organisation for Economic Co-operation and Development
PGEU	Pharmaceutical Group of the EU
PNH	Paroxysmal Nocturnal Hemoglobinuria
PO	Procurement Organizations
SoHO	Substances of Human Origin
T&C	Tissue and cell
TIF	Thalassaemia International Federation
UEG	United European Gastroenterology
UN	United Nations
WHO	World Health Organization
WMDA	World Marrow Donor Association
WP	Work Packages

## Introduction

The Joint Action *Piloting GAPP model approach for assessing and authorizing novel substances of human origin preparation PROCesses* (GAPP-PRO) is a European initiative co-funded by the European Commission within the EU4Health Programme.

During its lifetime (from February 15<sup>th</sup> 2024 to June 14<sup>th</sup> 2027), this project aims at testing and perfecting GAPP JA (GA 785269) methodology through the following actions:

- 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 Member States (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 medical devices and pharmaceutical fields;
- updating the EuroGTP II risk assessment tool extending the already available platform to other SoHO, namely faecal microbiota and breast milk;
- refining the GAPP Good Practice Guideline to authorization on preparation process in blood, tissue and cell establishments taking advantage of the results of the pilot tests as well as the opinions of the different professional and competent authorities that took part in the pilot tests.

## Disclaimer and EU Emblem

In accordance with the Grant Agreement, any communication activity related to the project must display the EU Emblem with the appropriate prominence and include the following disclaimer:

*“This [insert appropriate description, e.g. power point presentation, report, publication, conference, etc.] is part of the Joint Action “101128035/GAPP-PRO” which has received funding from the European Union’s EU4Health Programme (2021-2027). The content of this [insert appropriate description, e.g. power point presentation, report, publication,*

*conference, etc.] represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains”*

## Dissemination and Exploitation Plan

This dissemination and exploitation plan details and supports the dissemination, exploitation, and communication strategy to raise awareness about the GAPP-PRO JA to spread its main results, also beyond the official duration and proceed the long-term identity, which started with the previous GAPP initiative.

The communication strategy will target all relevant stakeholders, including policy makers and the general public across the EU. Given the duration of the initiative, it will be revised periodically on the basis of the feedback and the results achieved.

This document will present:

- visual identity (logo);
- target groups;
- dissemination activities, means and tool;
- sustainability.

The Italian National Blood and Transplant Centres (ISS/CNT-CNS) will lead the dissemination and communication activities in order to:

- define and establish the Consortium’s dissemination and communication strategy;
- manage the internal and external communication and proper dissemination of the project results and its deliverables;
- define and reach the target audience and stakeholders at the level of institutions, professional societies, policy makers and final users, including donor and patient associations;

- raise awareness of the target audience, stakeholders and community in general, as regards the project activities;
- ensure the proper visibility of EU co-funding;
- provide to the whole Consortium the means for dissemination and communication of the JA actions and outputs.

Given the pivotal role played by both the previous and the ongoing JAs within the new EU SoHO Regulation, the overall aim is to contribute to the creation/improvement of a network for distributing information related to the project implementation and the results that will complement the related items covered in the new forthcoming legislation. In order to maximize this result, the dialogue with DG SANTE SoHO Team will be constantly kept.

## Visual Identity (logo)

In order to have a strong identity and a clear visual identity, a dedicated logo was designed. The logo of the JA aims to highlight the link with GAPP and to underline that GAPP-PRO is its direct prosecution:

- the colours used are the same as those of the logo of the previous JA;
- the pictogram, an icon strongly representative of the original Joint Action, has been partially modified: at the bottom of the cross, the acronym PRO has been included;
- the position of the pictogram (cross symbol) has been moved on the right and at the bottom of the lettering (according to the graphic composition), so that the acronym PRO comes after GAPP;
- for the acronym PRO, the GAPP font and the colour of the inside of the cross have been used.

This structure recalls the idea of a butterfly flight with a strong good wishing meaning for the new JA. Therefore, the logo emphasizes the idea that GAPP JA took off like a butterfly in the sky.



Figure 1: GAPP-PRO horizontal logo



Figure 2: GAPP-PRO vertical logo

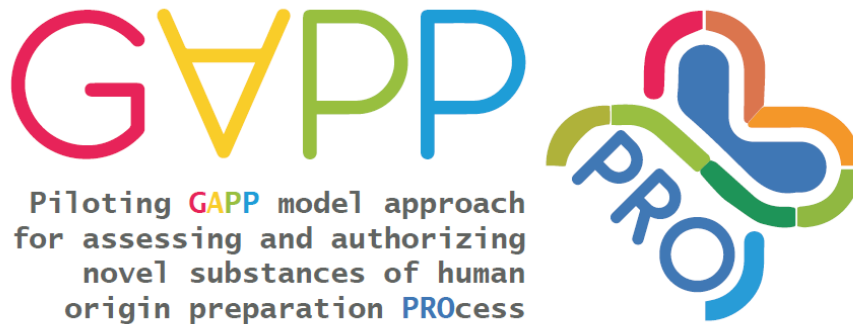


Figure 3: GAPP-PRO full logo



## Target groups

One of the main objectives is to identify and to reach the target audience and stakeholders, including EU and national policy makers, academic institutes, professional associations, end users and the public, in order to raise their awareness regarding the findings of the consortium and to encourage them to support their promotion/endorsement.

The target groups are herewith defined on the basis of three levels:

- institutional level (international/European and national competent authorities, policy makers and organizations);
- professional level (national and international professional societies e.g. in the fields of transfusion medicine, haematology, apheresis, internal medicine, etc.; whereas in the field of tissues and cells donation and transplantation, tissue and cells banks, gastroenterology units, etc.);
- final users (healthcare providers, donors and patients associations as well as the general public).

Effective dissemination, communication, and exploitation of findings are central to successful high-impact research, particularly whenever the project involves multiple groups. Given the project impact, dissemination should be made not only at international and national level but also targeted to regional and local actors.

As for the **institutional level**: regulators/legislators/technical bodies:

- EU MS Competent Authorities for blood and blood components, T&C and MAR, including pharmaceuticals and medical devices;
- Media Offices of all Competent Authorities;
- National health ministries or/and agencies;
- European Commission (DG SANTE, DG RESEARCH, DG DIGIT);
- ECDC;
- EDQM and its working groups;
- EMA;

- WHO;
- Members of the European Parliament;
- EU Health Attachés;

As for the European/international **professional societies**, such as:

- EBA;
- ISBT;
- ESHRE;
- IBMT;
- EAHP;
- PGEU;
- EFPIA;
- EBMT;
- EATCB;
- EMBA;
- EEBA;
- UEG;

As for **final users**:

- BTC establishments;
- procurement establishments;
- hospitals.

Patients:

- EPF;
- ALAN;
- CCI Europe;
- CLLAN;

- CML Advocates Network;
- EFAPH;
- EHC;
- LC;
- ITP Support Association;
- International MDS Alliance;
- MPE;
- MPN AN;
- PNH Global Alliance;
- EURORDIS;
- ESCF.

Donors:

- FIODS/IFBDO;
- WMDA;
- TIF Donors.

Further regional and local stakeholders will be identified in cooperation with beneficiaries and affiliated entities thus to reach the utmost dissemination of JA outcomes.

The involvement of key target groups is also deemed as significant to foster collaboration and synergy and ensure that they can contribute with their highly specialised knowledge to the updating of technical requirements for preparation processes. Moreover, the ultimate goal to ensure a high level of protection of both donors' and patients' health will encourage building a common harmonized approach on the topics related to the JA. This will result also in producing reciprocal advantages in enhancing technical and organisational skills of the multitude of actors. MSs will have the opportunity to learn from other MSs where regulatory systems may be consolidated in this particular field. Eventually, different target groups will get a better understanding on how to play their role in this specific activity.

As mentioned, any dissemination activity will have to be echoed by each member of the Consortium by attending local, national and international conferences to present the project activities and results to experts in the field of blood, tissues, cells and reproductive cells and by communicating the findings to the corresponding CAs and policy makers.

## Dissemination activities, means and tools

The mission and vision, as well as the outcomes of the project, will be disseminated to the above groups by using several communication means and tools, in primis the choice of a devoted visual identity, on which basis the different following tools will be developed. In particular:

- Project website: it will be specifically designed to be the main showcase for the results and achievements of the JA. It will contain the main information about GAPP PRO: objectives, short bios and photos of all the Work package leaders, the list of the key team members for each work package, the descriptions of both the organisation involved and the WPs. The website will focus on the Action deliverables, publications, results and background of the project and Consortium. The website will be maintained two years after the end of the project;
- Templates: file models for the preparation of meeting agenda and minutes, deliverables, technical and financial report, presentations and posters;
- Layman brochure: one layman version of the technical reports will be produced. They will contain a short description of the project and the aims of the work packages, as well as the list of all the partners involved in the Action. The state-of-the-art and results will be duly highlighted. In particular, the final brochure will describe the implementation process among MS, and the partners' conclusions and achievements;
- Newsletters: three digital newsletters will be issued to the target groups via the consortium partners' websites and other communication media deemed appropriate at national and international level to create maximum awareness of the state-of-the-art of JA. The Dissemination leader will be the editor of the newsletters and will be responsible for the overall dissemination; all partners will contribute to the contents production and

will disseminate the document/s in their own Countries;

- Press releases: involvement of press and media is a fundamental task to communicate and disseminate the JA results. Press releases will be multilingual. Each partner of the Consortium will translate it in its local language; launch it on the website and through all local communication channels, as much as possible, which maximize project awareness. During the JA, the Consortium will launch at least two press releases in newsfeed platforms such as Eurekalert and Alpha Galileo;
- Scientific publication: presentations and articles in peer-reviewed scientific medical journals will contribute to the further adoption the results of the JA. The beneficiaries of the Consortium will be invited to write and submit articles for publication. In order to ensure consistency in the dissemination of JA information through presentations and publications, a dissemination policy for publication and presentation will have to be agreed within the Consortium;
- Social media: social networks are another potentially useful dissemination tool and channel. JA's results may be disseminated through popular social networks such as LinkedIn. A GAPP PRO account will be created and frequently updated with contents approved by the WP Leader of the dissemination activities

These contents will be shared on the social media channels of the partners following a dedicated plan and a shared calendar;

- Events: besides the participation in key European and national conferences, devoted meetings will be organised to disseminate the initiative. Specific collaboration will be sought from DG SANTE SoHO Team in order to maximize the awareness and engagement of national CAs. Eventually, HaDEA officer will be informed about any communication activity performed and the official HaDEA communication channels cited whenever relevant.

Additionally, for the sake of the preparation of the Technical periodic report, all BEN and AEs will be regularly asked to provide the list of the dissemination activities carried out in the context of the joint action, including dissemination activities mentioned in the proposal or other ones as follows:

Dissemination activity name	
What? (type of dissemination)	Collaboration with EU-funded projects
	Conference
	Education and training events
	Meetings
	Other
	Other Scientific collaboration
Who? (target audience reached)	Industry, business partners
	innovators
	EU institutions
	National Authorities
	Regional Authorities
	Local Authorities
	Civil society
	Citizens
	Research communities
	Specific end user communities
	International organization (UN body, OECD, etc)
	Other
Investors	
Why? (description of the objective(s) with reference to a specific project output)	To be specified for each dissemination activity
Status of the dissemination activity	Delivered
	Ongoing
	Postponed

## Sustainability of dissemination actions

Dissemination is essential to define take-up actions, and take-up is crucial for the success of the JA and for the sustainability of outputs in a long-term perspective. A sustainable and

successful approach relies also on the development of solid partnerships and relations between GAPP and all the relevant stakeholders or networks that could help to maintain or expand the outputs of the JA, after the end of the EU funding.

Sustainability is about maintaining and continuing specific activities after the end of the initiative ensuring that the organisations of the Consortium continue to exploit the outcomes of the JA. To this end, the following actions seem to be of strategic importance:

- evaluation and continual quality improvement;
- expanding partnerships;
- identifying new funding streams and diversifying sources of funding;
- building a case for policy change;
- made results (documents and tools) available after the end of the Action.

Most of all, it is important to ensure that the results of the GAPP-PRO JA are visible and available, especially through the project website, so that the target audiences can access them, learn from them, adapt them to their own needs and even build on them and take them to the next level.

All public documents of the project will remain available for two years after the JA expiration, on the GAPP-PRO website. After the expiration of the website, public documents will be anyway available to the EC project website.