Newsletter 3

(Nov 2020)

FacilitatinG the Authorisation of Preparation Process for blood, tissues and cells

GRANT AGREEMENT NUMBER - 785269
May 2018-April 2021

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Introduction

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:

01 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,

02 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

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

The GAPP Joint Action has just passed its midterm and considerable progress has been accomplished in all parallel activities and work packages. The first results are available and reveal that the CA are forwarding towards a more homogeneous environment for the preparation processes of blood, tissues and cells. The Joint Action is undertaken by sixteen (16) European countries, with representatives from CA, 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 CA level. Also, European Organizations contribute their scientific experience. GAPP consortium so far includes 24 beneficiaries (1 coordinator and 23 associated) and 15 collaborating stakeholders.

3rd Newsletter

In this third 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. Eight major technical meetings were held during this 9 month period:

a. **WP8 Technical Meeting, February 5, 2020**
b. **WP7 Technical Meeting, February 27, 2020**
c. **Coordination Meeting, April 7, 2020**
d. **WP8 Technical Meeting, April 20, 2020**
e. **WP5 Coordination Meeting, May 20, 2020**
f. **WP7 Technical Meeting, June 15, 2020**
g. **WP7 Technical Meeting, September 15, 2020**
h. **WP10 Technical Meeting, September 24, 2020**

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. Due to the impact of COVID-19 pandemic the original timeline of the Action will be extended till October 2021. There is still one year of Project ahead, meaning a lot of goals to accomplish.

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

Technical Meetings & Workshops

This issue, is the third regular edition of the GAPP Newsletter. It highlights mostly the efforts and progression of the Technical Work Packages (WPs) in order to enhance and strengthen the insight of stakeholders. Despite the COVID-19 pandemic, eight major Technical Meetings were held, mostly virtually, during this 9-month period:

a) WP8 Technical Meeting, February 5, 2020. A joined SANTE-SOHO and GAPP WP8 Technical meeting on "Effectiveness and outcome measurements for Blood, Tissues and Cells (BTC)" took place in SANTE premises in Brussels on February 5, 2020 (host: Stefaan van der Spiegel, DG SANTE). During the meeting the GAPP deliverables D8.1 (catalogue of existing clinical data to provide information on the quality and safety of human BTC therapeutics once applied to patients) and D8.2 (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 BTC therapeutics) were presented; the GAPP deliverable D8.3 (methodological framework to evaluate quality and safety of human BTC therapeutics based on clinical outcome data requested for authorization processes upon introduction of innovation to the current processing and testing protocols for human BTC therapeutics) was discussed for drafting.

b) WP7 Technical Meeting, February 27, 2020. Due to the SARS-CoV-2 outbreak, a GAPP WP7 video conference Technical Meeting replaced the live meeting that had been scheduled to take place in Langen, on the same date. The aim of the Technical Meeting (host: Fimea, FI; and ABM, FR) was to gather technical inputs for drafting the GAPP deliverable D7.1 (Technical Annex 2 to Overall guidance: Assessing the quality and safety of donor testing, pathogen reduction and sterilisation steps as part of preparation process autorisation - PPA). Anu Puomila (Finnish Medicines Agency, FIMEA) informed about the scope and aims of the draft guidance developed by WP7 and Winfried Kammer (Paul-Ehrlich-Institut, DE) introduced the concept of WP9 i.e. development of database in which GAPP WPs' outputs will be integrated, as for knowledge sharing between Member States' CA. External Experts, GAPP WP leaders and CA representatives participated in this video conference.

c) Coordination Meeting, April 7, 2020. A GAPP WP leaders video conference organized by the GAPP coordinator Paola Di Ciaccio (Italian National Transplant Centre, Italian National Blood Centre) took place on April 7, 2020. The aim of this video conference Coordination Meeting was to have an update from the technical WP leaders after the intermediate meeting and discuss he impact of the COVID-19 outbreak on the GAPP time schedule deliverables. The GAPP WP leaders and CA representatives were present in this meeting.

Technical Meetings & Workshops

d) WP8 Technical Meeting, April 20, 2020. A GAPP WP8 video conference Technical Meeting aiming to review and finalize the deliverable D8.3 (methodological framework to evaluate quality and safety of human BTC therapeutics based on clinical outcome data requested for authorization processes upon introduction of innovation to the current processing and testing protocols for human BTC therapeutics) took place on April 20, 2020 (hosts Fimea, FI; and BST, ES). GAPP WP Leaders, GAPP Coordinators, Associated & Collaborating Partners, External Experts and DG SANTE Representatives participated in the video conference. In addition to the D8.3 work progress, the EU programme of COVID-19 convalescent plasma collection and supply was presented by Deirdre Fehily & Stefaan van der Spiegel (DG SANTE). The project was promoted by DG SANTE in collaboration with the European Blood Alliance (EBA). WP8's experts and GAPP WP leaders were invited to express their interest to collaborate in this EC's initiative.

e) WP5 Coordination Meeting, May 20, 2020. A GAPP WP5 video conference workshop (Development of Overall Guidance on Organisation of PPA System) took place in May 20, 2020 (hosts: HPRA, Ireland and CatSalut-OCATT, Spain). It was decided that the Guidelines will be organized according to the following structure: Introduction, Background, Part A (Risk Assessment: Definition of novelty; Significant changes), Part B (Application Process: New application; Variations), Part C (Technical Annexes), Part D (Review and Evaluation; Authorisation), Part E (Framework for Competent Authority). The participants discussed in detail every chapter of the Guidelines.

f) WP7 Technical Meeting, June 15, 2020. A GAPP WP7 video conference Technical Meeting aiming to review and modify the deliverable D7.1 (Technical Annex 2 to Overall guidance: Assessing the quality and safety of donor testing, pathogen reduction and sterilization steps as part of PPA) took place in June 15, 2020 (hosts: Fimea, FI; and ABM, FR) in the presence of GAPP WP leaders, coordinators and external experts. Requirements for general validation, laboratories and testing kits, methods for pathogen reduction, sterilization and microbiological quality testing of the final BTC product were extensively discussed and agreed. Interactions between WP9 GAPP database and WP7 were also discussed.

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Technical Meetings & Workshops

g) WP7 Technical Meeting, September 15, 2020. A GAPP WP7 video conference Technical Meeting aiming to finalize the Deliverable D7.1 (Annex 2 for the GAPP Overall Guidance) took place in September 15, 2020 (hosts Fimea, FI; ABM, FR) in the presence of GAPP WP7 Experts and Associated Partners, leaders of other GAPP WPs and SANTE SOHO representatives. The participants reviewed and discussed all comments and modifications proposed on the draft version of D7.1 that had been distributed before the Meeting. It was agreed that the D7.1 document could be circulated for BTC CAs comments and subsequently for GAPP External Advisory Board assessment.

h) WP10 Technical Meeting, September 24, 2020. The GAPP WP10 video conference first Technical Meeting was organised in September 24, 2020 (hosts: Izabela Uhrynowska-Tyszkiewicz and Artur Kamiński; National Centre for Tissue and Cell Banking, Poland). WP10 works include developing the content of training for inspectors, conducting two training sessions for inspectors, developing the content of the training manual for inspectors. It was discussed that due to the epidemic situation, both the work and training sessions will have a changed formula i.e. all activities will be carried out remotely. Details on the training tools (platforms) and means (lectures, webinars etc) were discussed as a starting point.

GAPP faces

Ms Claudia Carella

Master of Science in International Relations with specialised training in European Project. Claudia is working for the Italian National Transplant Centre (CNT) and she is a co-key team member of the Work-package 1 of the GAPP Joint Action.

Dr Aurora Dragomiristeanu

General Director of the Romanian National Registry of the Hematopoietic Stem Cells Voluntary Donors. Thanks to her experience as work-package leader in EU Joint Action, Aurora is leading the WP4 of GAPP Action.

> **"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"**

Prof. Helen Papadaki

Professor of Haematology, School of Medicine, University of Crete. Head, Department of Haematology, Autologous Haemopoietic Stem Cell Transplantation Unit, Public Umbilical Cord Blood Bank, University Hospital of Heraklion, Crete, Greece. Helen is the Coleader of the WP2 of GAPP JA, related to the Dissemination & Communication, on behalf of the 7th Health Region, Crete.

Ms Tihana Cikač

Tihana has graduated from the Faculty of Science, University of Zagreb and has a master's degree in experimental biology. She has completed a year of professional training within the Croatian Ministry of Health, with special emphasis on health protection activities. Tihana currently works on a position of a full-time project manager (GAPP, WP3) in the Service for Blood, Cell and Tissue Inspection.

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Events with GAPP visibility

46th EBMT (European Society for Blood and Marrow Transplantation) Annual Meeting

The GAPP Joint Action was present with a virtual Booth in the 46th Annual Meeting of the EBMT (European Society for Blood and Marrow Transplantation), which took place virtually between 29 August – 1 September 2020. Project's coordinator (Paola Di Ciaccio) and manager (Claudia Carella) were present during the opening hours of the virtual Exhibition, answering the questions and engaging with the participants who were viewing the exhibition. A video, banners, documents and links were included to the Booth that gave great visibility to the GAPP's WPs and results. According to the conference metrics, approximately 100 participants visited the GAPP Booth.

Events with GAPP visibility

36th ESHRE (European Society of Human Reproduction and Embryology) Annual Meeting

GAPP Joint Action was present with a marvelous virtual Booth at the 36th ESHRE (European Society of Human Reproduction and Embryology) Annual Meeting, which took place virtually between 5-8 of July 2020. In the Booth, the overall scope, the goals and developments of the Action were presented through electronic material i.e. a big screen with a GAPP promotional video and interactive screens with ppt, infographics, newsletters and brochures. Special emphasis was given to the GAPP developments that are anticipated to define how future IVF therapies will be authorised in Europe. Additional information on the third Public Health programme and EC initiatives in substances of human origin (SoHO) field were also available in the GAPP Booth.

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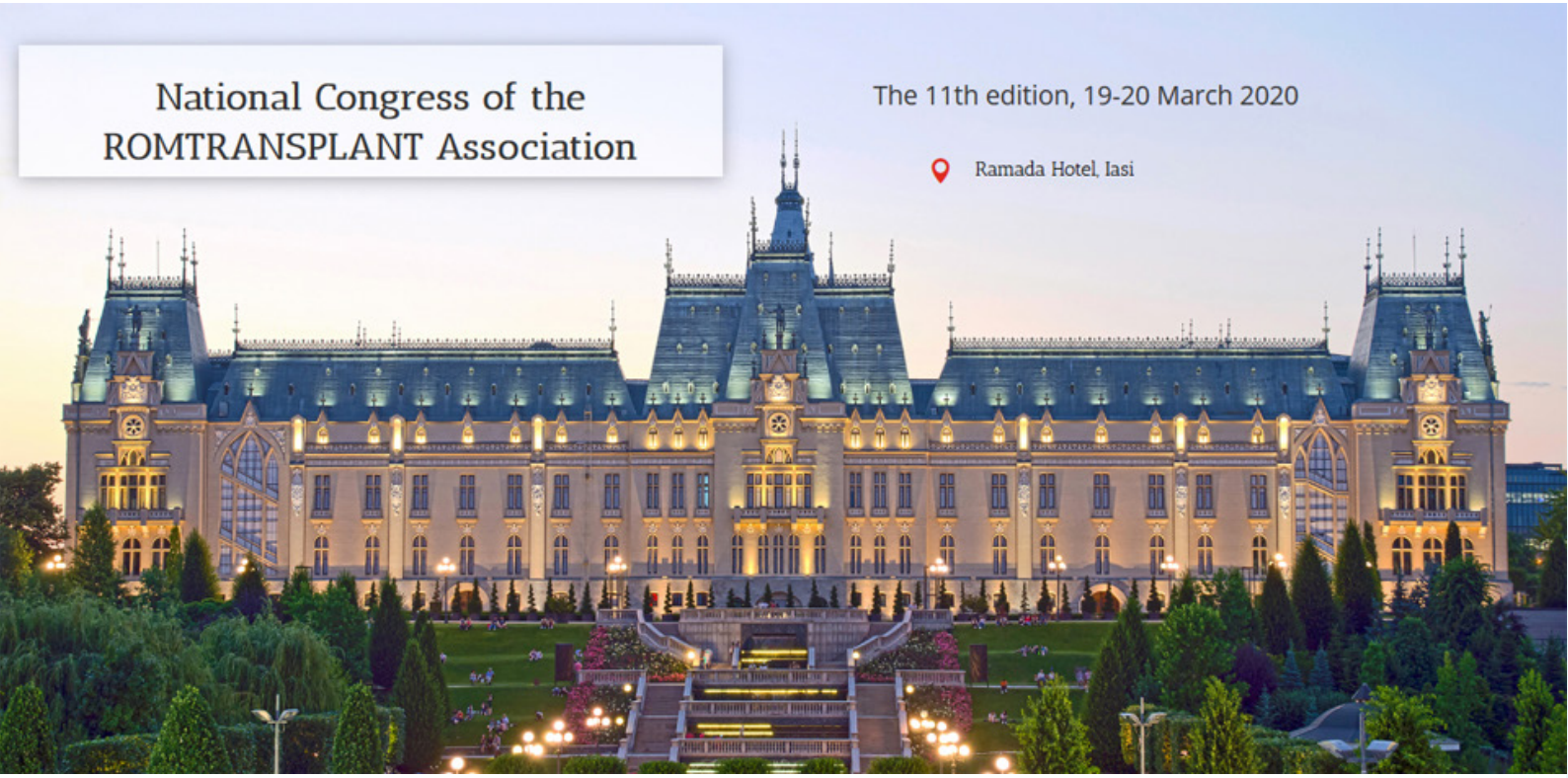
Events with GAPP visibility

11th virtual Congress of ROMTRANSPLANT Association 23-25 September 2020

Presentation "GAPP Project - Preparing the accreditation of the changes in donation, procurement and collecting, processing, storing and distribution of haematopoietic stem cells", presentation by Dr Aurora Dragomiristeanu – Registrul Roman Al Donatorilor Voluntari de Celule Stem Hematopoietice din Romania



Recent Advantages per Area

WP1 GAPP CONSORTUM COORDINATION
WP Leader: Istituto Superiore di Sanità (ISS – CNT – CNS)

During this part of the JA, WP1 on Coordination focused its effort on tracking and checking the activities performed by the Consortium in order to avoid any delay on the schedule. Where they occurred, the WP1 team helped the other WPs leaders to make up for lost time and to justify the postponements to CHAFEA.

From an administrative point of view, hard challenges arose:

1. Managing the changes in the Consortium due to the withdrawal of three beneficiaries (one in 2018 and two in 2019) leading to two amendments.
2. Handling the lockdown forced by the SARS-CoV-2 outbreak. After the last residential meeting, the Intermediate Meeting held in Rome from 29 th to 30 th of October 2019, the CNT-CNS staff convened remotely a WP leaders videoconference meeting on April 7 th 2020 to have an update of technical activities and the impact of the pandemic on GAPP route map.
3. Meanwhile, the time has come to deliver the first technical and financial report. CHAFEA approved the technical one and requested clarifications on some costs statements. Associated Partners are reshaping them, and the final version of the financial report is all almost ready
4. the intermediate technical report has been approved in July 2020.

Concerning the original contents foreseen for the deliverables, WP1 haematologist supported the idea to enlarge, in the framework of WP5, the EUROGTP II risk assessment tool also to the blood group and to apply the Product/Process authorization procedure to COVID-19 convalescent Plasma. BST will conduct this task with the support of the expertise of NHSBT as co-leader of EUROGTP-II project.
Great effort was put in place by the whole Consortium to minimize the impact of COVID-19 pandemic on the Action timetable. Indeed, the coordination team is thankful to all WP leaders, beneficiaries and collaborative stakeholders for the never-ending support to the outcome of GAPP.

WP2 DISSEMINATION
WP Co-Leaders: PGH + HRC

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 to the stakeholders engaging 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, acting as a document repository, is being regularly renewed with material produced by the Joint Action beneficiaries (work documents, deliverables, minutes etc.) to facilitate the internal communication among GAPP beneficiaries.

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Recent Advantages per Area

WP2

The COVID-19 era has led to an adaptation of our communication and dissemination procedures, making them compatible to the necessary social distancing. However, WP2 has released an extra newsletter issue, dedicated to the project outcomes, as illustrated during GAPP interim meeting.

Moreover, GAPP had an emphatic presence in the 36th ESHRE virtual Annual Meeting (European Society of Human Reproduction and Embryology), which took place virtually between 5-8 of July 2020 and the 46th virtual Annual Meeting of the EBMT (European Society for Blood and Marrow Transplantation), which took place between 29 August – 1 September 2020. The consortium is thankful to ESHRE and EBMT for giving such great opportunity to GAPP action to be disseminated in such relevant congresses.

WP3

EVALUATION
WP Leader: MoH HR

The main goal of WP3 is to ensure that the project is being implemented as planned, that it reaches its objectives and results in high quality deliverables. All WP3 deliverables have been submitted, except for one – Final evaluation Report (due date is in the last month of the GAPP lifetime).
The work of WP3 is being carried out in two aspects - internal and external evaluation. Work methodology of an internal evaluation consists of the following qualitative and quantitative methods:

- Assesment of the outputs (milestones and deliverables)
- Surveys (focus on the assesment of the GAPP meetings)
- Observation (continuous monitorng of GAPP activities)
- Timeline tracking (continuous monitorng of GAPP activities)

The main difference between internal and external evaluation aspects is the collaboration with the GAPP External Advisory Board. The board gathers seven internationally acknowledged experts, as listed in the following table:

Field of expertise	EAB member
Blood	Johanna C. Wiersum , TRIP National Hemovigilance and Biovigilance Office, Netherlands
Tissues	Johan Guns , Vrije Universiteit, Belgium
HSC	Ineke Slaper Cortenbach, Netherlands
ART	Alessandra Alteri, San Raffaele Scientific Institute, Italy
TTD Testing	Ines Ushiro Lumb, NHS Blood and Transplant, United Kingdom
Microbiology	Veroniek Saegeman, University Hospital Leuven, Belgium
Clinical trials	Andrijana Tivadar, Slovenian Pharmaceutical Society (SFD), Slovenia

Recent Advantages per Area

WP3

For each deliverable generated, EAB provides a comprehensive expert feedback.

Contribution and collaboration of both associated and collaborative GAPP partners are a crucial precondition for a successful evaluation.

WP4

INTEGRATION IN NATIONAL POLICIES AND SUSTAINABILITY
WP Coleaders: RNDVCSH, Romania and ISS-CNT-CNS, Italy

WP4 started in April 2020 and is conducted by the Registrul National al Donatorilor Voluntari de Celule Stem Hematopoietice, from Romania with the support of the Italian National Institute of Health, National Transplant and Blood centres. The Aim of WP4 is:

- To set up a plan to describe the potential of GAPP results for integration in policies (at national, regional or local levels)
- To ensure the sustainability of the JA activities at national or local or regional level.
- Draft a common proposal for supporting a sustainable implementation in single countries.

The work will focus on implementation and thereby sustainability at two levels.

- At the CA level for regional/ national policies and eventually within Europe.
- At the professional level for acceptance and thereby integration into good practice at national/ European level.

A Swedish expert is supporting the activities of WP4 related to the implementation on national legislation in cooperation with the Swedish tissue council (SALAR) collaborating stakeholder in the action. A draft plan for the implementation of GAPP outcome in Sweden has been drafted in July 2020 and is presently ongoing.

WP5

DEVELOPMENT OF OVERALL GUIDANCE ON ORGANIZATION OF PPA SYSTEM
WP Leader: HPRA, Ireland; OCATT, Spain

WP5 has the objective of developing an overall guidance on how a preparation process authorisation (PPA), should or could be organised. Two deliverables have been drafted and sent to the External Advisory Board. D5.1, involves a review of the previous European projects to be applicable to blood establishments. D5.2 contains a review of the outcome and conclusions of the survey that was sent to the European Competent Authorities, it also includes a revision of a desk-based review of PPA in other fields, and the conclusions of the two multi country-workshops that were held at the facilities of the European Commission in October 2019, for Tissue and Cell CAs, and February 2020 for Blood CAs. WP5 is currently designing the main contents and the structure of the Overall Guidance on Organisation of PPA system and it will be presented soon to the rest of the WPs' leaders.

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Recent Advantages per Area

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, ANSM, EBMT

Work Package 6 has two parts: the identification of the criteria that need to be taken into account in authorising products and preparation processes and the identification and description of methods to evaluate them. A necessary preliminary step was to identify all the processes and products from a wide range of sources, including, but not limited to, European legislation and EDQM guides.

WP6 provisionally submitted Milestone 24 in July 2020 completing the first part of the work.
In Rome in October 2019, the expert groups started part II; identifying evaluation methodologies supporting the use of risk-based approaches and integrating the results of EuroGTPII whilst building on the extensive experience of MHRA(UK), PEI(D) and ANSM(F).
Currently WP6 is taking stock of the work that has been accomplished in part II and the availability of experts for its completion. There should be a draft of the evaluation methods section by the end of the year. We are sharing, our preliminary results with WP5, WP9 and WP10 and WP9 has already incorporated the structure of our criteria into the integrated data model presented in D9.1.

Prior to the Oct 2019 meeting in Rome the WP6 expert sub-groups were restructured, with a specific tissues group led by Dr Isabelle Martinache (Agence de la biomédecine ABM) being separated from a specific Haematopoietic Stem Cells group led by Eoin McGrath (EBMT). MHRA(UK) also requested that the leadership of the Blood Expert Subgroup be transferred to the ANSM(F) represented by Dr Imad Sandid. The expert subgroups continue to be productive and active and led by highly competent domain experts (Professor Dominique Royère continues to lead the MAR group).

Finally, Katia Bruneau's(ABM) contract regrettably reached its term at the end of June 2020 and we miss her unique energy; Nigel Strang (ABM) accepted Samuel Arrabal's request to continue her excellent work as of June 2020.

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

WP7 is currently finalizing its main outcome, the Technical annex 2 on assessing the quality and safety of donor testing, pathogen reduction and sterilization steps as part of Preparation Process Authorization (PPA). Blood, tissues and cells (BTC) for clinical use bear the risk of carrying number of infectious agents, which may result in their unintentional transmission, which could then lead to disease and even death in recipients.

WP7

Appropriate and reliable laboratory testing of each donation and/or donor, control of reagents, pathogen reduction, as well as, where appropriate, post-processing microbiological testing of BTCs, can substantially reduce the risk of transmission, and improve the overall safety of BTCs. In drafting the guidance, WP7 leaders have worked with 63 experts from GAPP associated and collaborating partners, representatives of Competent Authorities, European organizations, Blood and Tissue Establishments and clinicians.

WP8

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

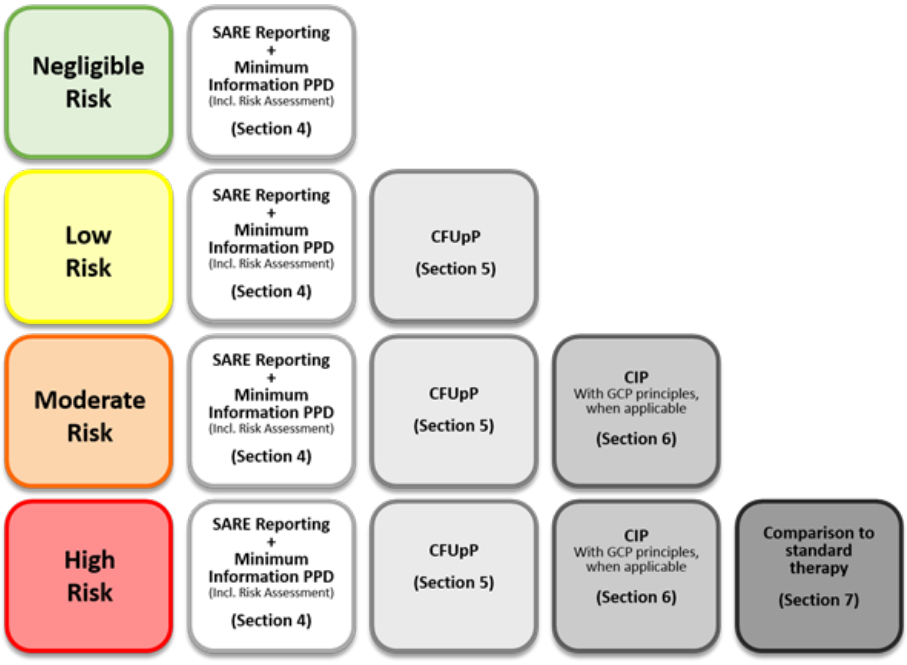
WP Leader: Finnish Medicines Agency (Fimea; Finland), Barcelona Tissue Bank (Spain)

The WP8 group, supported by the valuable collaborations of 46 experts from of 28 organisations, amongst Associative and collaborative Partners, representatives of Competent Authorities (CA), clinicians/surgeons, embryologists and tissue bankers, has concluded and submitted to CHAFEA its 3rd deliverable: "Annex 3. Guidance on how to evaluate plans to collect BTC recipients' clinical outcome data upon introduction of innovation to the current BTC processing protocols".

This guideline establishes a methodological framework required to perform a standardised assessment of clinical data as part of Preparation Process Authorisation (PPA), and provide CAs with key principles as to:

- which factors should be considered by CAs when assessing the clinical component of a Preparation Process Dossier (PPD) for completeness and suitability;
- when a Clinical Follow-up Plan (CFUpP) or a Clinical Investigation Plan (CIP) should be requested in order to support the authorisation of a new BTC preparation process and/or therapeutic application;
- what elements should be included in the CFUpP or CIP;
- what type of clinical data would be required to determine the safety and efficacy of human Blood, Tissues, and Cells (BTC) applications for therapeutic use in recipients.

Moreover, WP8 proposes a standard plan for collecting clinical data, proportional to the risk level (Figure).



The extent of plan for collecting clinical data included in the clinical component of the PPD is based on the risk level.

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WP9 KNOWLEDGE SHARING ON PPA BETWEEN EU CAS
WP Leader: PEI, Germany

WP9 designs a concept and a demonstrator for an online platform. The online platform is developed to support a complete preparation process authorization (PPA) for blood, tissues and cells (BTC). This comprises application for PPA by blood/tissue establishments and assessment of PPA application by national competent authorities. The online platform will further serve for knowledge sharing of data on PPA procedures. This includes information on national authorization procedures and national/international requirements and recommendations. WP9 subcontractor, Fraunhofer Institute for Software and Systems Engineering, is in charge of programming the demonstrator.

As a first step, WP9 created a data model illustrating how the information from WP6, WP7 and WP8 will be integrated into the online platform. The finalized data model is already submitted as Deliverable 9.1. Secondly, WP9 started developing a preparation process dossier (PPD) by adapting the Common Technical Document format for BTC. The PPD, as a framework and template for PPA application, will be the core of the online platform and Deliverable 9.2. Finally, in Deliverable 9.3, WP9 will combine Deliverables 9.1 and 9.2 and provide a concept for the online platform. Functionalities, such as authorisation (i. e. benefit-risk analysis) and a description of how the online platform and templates for PPA application will be adapted and updated, will be addressed in Deliverable 9.3.

WP10 TRAINING COURSES AND MANUAL FOR TRAINING
WP Leader: KCBTiK/NCTCB, Poland

On the basis of agreed documents: “Overall Guidance on organization of PPA system” and technical annexes, this WP will organize two e-learning training courses (ECTs credit) and prepare the “Manual for training CA inspectors that assess and authorize preparation processes of tissue, cell, and blood products”, to disseminate the approach throughout Member States.
Training courses will be organized remotely open to all Member States countries, as well as to Serbia and Moldova.
On Sept. 24, 2020 during the first WP10 telco with the WP Leaders it was discussed the general design of the course and participation/role of each partner
Within mid-November, 2020 WP10 Leader and Coordinators will share:

- Announcement of the course with main objectives, number of participants, participant selection criteria, number of ECTS
- Draft programme of the course with topics, reference documents and potential facilitators/technical experts
- The course will foresee the use of 2 tools:
- the University of Warsaw platform, which will be mainly used for the storage and consultation of documentation/material and for recorded lectures and use of a forum for discussion;
- webinars platforms such as zoom or gotomeeting for webinars/live lectures/live exercises (e.g. a working pool will be organised for each group (for each SoHO) for carrying out the exercises and consequent discussion and results presentations).

The course will be delivered in 2 editions (5 weeks each):
- 31/05/2021 – 02/07/2021
- 6/09/2021 – 8/10/2021

Deliverables Produced

D.8.1 - 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. (Oct 2019)

D.8.2 - 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. (Dec 2019)

D.9.1 - INTGRATED DATA MODEL (Oct 2020)

D.8.3. - TECHNICAL ANNEX 3 TO OVERALL GUIDANCE: ASSESSING CLINICAL DATA AS PART OF PREPARATION PROCESS AUTHORISATION (PPA) (Oct 2020)

D.7.1. - TECHNICAL ANNEX 2 TO OVERALL GUIDANCE: ASSESSING THE QUALITY AND SAFETY OF DONOR TESTING, PATHOGEN REDUCTION AND STERILISATION STEPS AS PART OF PREPARATION PROCESS AUTHORISATION (PPA) (November 2020 - External Advisory Board evaluation)

D.5.1. - EXTENSION OF THE OUTPUTS OF PREVIUOS PROJECTS, VISTART WP5-B, EUROGTP-II, ECCTR, TO BE APPLICABLE TO BLOOD ESTABLISHMENTS (Aug 2020 - DRAFT - Final Comments)

D.5.2. - REPORT ON THE OUTCOME AND CONCLUSIONS OF THE SURVEY, DESK-BASED REVIEW OF PREPARATION PROCESS AUTHORISATIONS IN OTHER FIELDS AND THE MULTI-COUNTRY WORKSHOP (Aug 2020 – DRAFT – Final Comments)

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GAPP PROJECT

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May 2018-April 2021

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