Table Of Content

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells

JA2015 - GPSD [705038]

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Project abstract

GAPP Joint Action (facilitatinG the Authorisation of Preparation Process for blood and tissues and cells) is a 36 months JA aiming at facilitating the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments (BEs and TEs). Particular attention will be devoted to innovative processes that might come up taking advantage of the work developed in previous EU funded projects/actions. This Joint Action will clearly contribute to the implementation of Union legislation in the fields of human tissues and cells, blood, providing tools and training to increase harmonisation of those MS activities that regulate the areas of blood transfusion, transplantation of tissues and cells and assisted reproduction, in strong abidance with art 4.5 of Annex I of Regulation 282/2014. These are fields of healthcare that involve a considerable amount of movement of donated substances of human origin between MS and also movement of citizens between MS for treatment, particularly in the field of assisted reproduction. The aim of the action is to prepare a “Good Practice Guidelines to authorisation and preparation process in blood, tissues and cells” and its three technical annexes respectively on i) authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution (divided in three part blood, tissues and cells, and reproductive tissues and cells); ii) assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA; iii) assessing clinical data as part of PPA. In addition to this it will be built a model and a tool to facilitate sharing of information among European Union Competent Authorities and a number of CA inspectors will be trained specifically to assess and authorise preparation processes of tissues, cells, reproductive cells and blood products.

Work package

Work Package 1: Coordination of the action

Start month: 1
End month: 36
Work Package Leader: ISS-CNT-CNS

WP1 will carry out the following activities:
Task 1.1- Organization of general plenary coordination meetings, where Steering Committee will convene: Kick-off (M2), intermediate meetings (M18) and final meeting (M36); interim WP meetings for reaching agreements on specific issues, developing work, and exchanging relevant information, including working progress will be held by conference calls. The final meeting will take place together with the final dissemination conference.
Task 1.2 Project working bodies (Project Committee will be constituted by all partners involved in the Consortium; WPs Steering Committee will be composed of the members of the coordination unit and the leaders of the WPs, being this Steering Committee an operational body for collective decision-making and reporting on the execution of the project).
Task 1.3 A Manual for the financial and administrative management of the JA will be prepared and circulated among partner, where the different reporting periods will be defined, along with management and financial rules and procedures (M4).
The General Management team will include two scientific managers, CNT and CNS General Directors, that will have overall responsibility for the whole joint action, two project management experts, a senior biologist team leader and a senior haematologist leader plus two technical coworkers. Project managers will supervise all the actions and works performed and steer the coordination team/unit.
The whole team, constituted by CNT-CNS staff, will monitor the progress of the Joint Action transversally and vertically, will establish communication with the steering committee on a regular basis, will report to the Directors of the Joint Action.

Work Package 2: Dissemination & Communication

Start month: 1
End month: 36
Work Package Leader: PGH

THIS WP WILL BE CO-LEAD BY THE PAPAGEORGIOU GENERAL HOSPITAL AND THE 7TH HELAHT REGION OF CRETE.

WP2 is dedicated to the dissemination of the action and its deliverables. Dissemination refers to the process of making the results and deliverables of the action available to the stakeholders and a wider audience.
Here all actions planned to ensure that the results and deliverables will be made

available to the stakeholders and can be used by them will be described. WP2 activities will include the development of the dissemination plan, a stakeholder analysis, identification of target groups, adequacy of channels used to reach them, and actions to ensure proper visibility of European Union co-funding.
The dissemination strategy should pay attention to the transfer of knowledge and to the processes needed for embedding and future take-up. The sustainability of the dissemination actions will be properly addressed.
The Dissemination WP team will include two Project Managers (one from Papageorgiou General Hospital and one from the 7th Health Region Greece) who will have the overall responsibility of the WP, one project mananger expert who will support and monitor all dissemination activities, two haematologists experienced in preparation processes on blood, tissues and cells, two highly qualified administrators, two administration staff, three information technology experts and one web graphic designer. The whole team consists of the staff of the Papageorgiou General Hospital and the 7th Health Region/University Hospital of Heraklionand two subcontractors (one dissemination/communication expert and the graphic designer). An experienced conference organizer will be also subcontracted for the final conference organization
Task 2.1 – Dissemination and Communication Strategy (M1-M36)
The task will define a detailed dissemination strategy to ensure high visibility and impact for the project. In specific, a dissemination plan covering all the duration of the project will be authored describing the aims and objectives of the JA, the actions to be disseminated, the target audiences/groups and stakeholders, the benefits to end users, the dissemination methods/activities, the timescales and responsibilities of the members of the team, the targets, the estimated costs, the evaluation and criteria for success. This task will also include planning for scientific publications in highly-ranked, open access journals, presenting the project concept, vision and results. Interaction and synergies with relevant initiatives/bodies/organizations will also be defined. Emphasis will be given on establishing measures as regards the sustainability of project outcomes. The dissemination strategy will be revised periodically based on the feedback and the achieved results to ensure that the targeted events maximize visibility and that the dissemination activities reach the targeted audience.
In this frame, a dissemination meeting will be held before the revision of the Dissemination Plan, in order to ensure that all partners are "in the same page" regarding the necessary dissemination and communication activities.
Task 2.2 – Dissemination and Communication Package (M1-M36)
A multi-strand approach will be used to ensure the effectiveness of the dissemination actions of the Consortium. This includes:
2.2.1 Configuration of the project Identity: Design the project logo, production of a design for printed material, production of banners, posters, flyers, preparation of the newsletters, production of video material, as well as official project templates for PowerPoint presentation. The Layman Brochure will be as well developed at month 3. The Brochure will address to all target groups including general public and it will contain a short description of the project, the aims of the work packages as well as the list of all the associated and collaborating partner organizations involved in the Action. A downloadable electronic version will be available in the

Work Package 3: Evaluation

Start month: 1
End month: 36
Work Package Leader: MOH - HR

The progressive achievements of Action activities and quality of deliverables will be continuously monitored and reported to the PPM. All associated partners and project events participants will contribute to the work of the WP3 by providing their own evaluation of all events attended. EAB will give expertise within their competences in evaluation of specific scientific/expert issues addressed in events and outputs of the Action where such an expertise is applicable.

The work will be carried out in two aspects: internal and external evaluation. Within all relevant project's events (including outputs) following elements will be evaluated:
-organisational elements (venue, traveling organisation, accommodation and related information…),
-technical elements (core materials and information flow, course, content and goal of the event, etc) and
- professional/scientific elements (deliverables).
The WP leader will produce an interim and final report, with executive summary shared with internal and external stakeholders. The final evaluation report will be focused on the outcomes and the reached objectives but also on the impact of the Action having in focus particularly sustainability of outcomes. Evaluation reports will be a standing item on Steering Committee meeting agendas, ensuring that quality of outputs in both means accuracy and contemporaneity is always a top priority.

At the beginning of the project, in cooperation with EAB where applicable, will be defined sets of indicators according to SMART criteria (paying in particular attention to have quantifiable indicators wherever possible) to assess performance. Set of indicators will be established for each specific objective of the project and will comprise:
- Output indicators linked to results
- Impact indicators linked to objectives
For single deliverable quality and applicability will be assessed based on, for example, following quality indicators:
timelines of outputs
comprehensiveness of collected data
critical/analytical nature of conclusions
clarity of conclusions/proposals
realistic nature of conclusions/proposals
adequacy of MS representation
clarity of information presented and recorded.

Surveys will be conducted through questionnaires structured as following:
enabling analysis and grading
reasonably short (up to 10 questions)

simple language
minimal likelihood of misunderstanding
close ended format (fixed answer set)
dichotomous questions (yes/no) preferred
requests for narrative answers avoided
even number rating scale (to avoid „golden middle" answers)
opportunity for expressing opinion (one open ended question)

Through the whole duration of the project WP leader and EAB will tightly cooperate aiming to produce timely and harmonized WP3 outputs. To achieve that leader and EAB will have 2 technical meetings which can be organized as video/teleconference if considered appropriate or back-to back to other project event (such as technical or plenary meeting for example).

Task 3.1. Definition of a project evaluation plan
In the first 6 months of JA lifetime project evaluation plan will be defined.

Task 3.2 Internal evaluation
Through the task all relevant project's events and outputs, such as technical meetings, plenary meetings, workshops/trainings, deliverables etc. will be assessed and evaluated.
The work methodology will include:
1. Data recording out of routine documentation of horizontal WPs and pre-release deliverables (training materials, guidelines, operations manual, recommendations, results of pilot projects, etc.),
2. Surveys,
3. Observation (support, early reaction, data security) with a calendar of milestones.

Task 3.3. External evaluation
Through the task all professional/scientific elements of each project's event and output, such as technical meetings, plenary meetings, workshops/training, deliverables etc will be assessed and evaluated under guidance and with inputs of EAB, to be composed of 6 internation

Work Package 4: Integration in national policies and sustainability

Start month: 24
End month: 36
Work Package Leader: IVO

WP4 will set up a model for CA´s in the MS to incorporate the results of the JA into policies at national/local level. Along with such policies WP4 will provide additional input to the work of WP2 (dissemination) and evaluate the acceptance (at the CA and the professional level) of the results in this JA. Toward the end of the action (M30) the analysis of possible barriers and obstacles to integration and

sustainability of JA results in single countries will be performed as part of the general survey on integration in national policies and recommendations for overcoming these will be added as parte of final sustainability report. Consensus about the criteria in the process for authorisation when introducing new methods in Blood, Tissues and Cells including ART, will eventually create recommendations of good practice among the professionals and acceptance of future regulations. The issues and plans for development and subsequent sustainability of the knowledge-sharing platform whose concept model will be defined under WP9 will be as well analysed and clarified.

At the CA level:
In particular the deliverables from WP5 will provide the basis for recommendations, depending on the various institutional organisations in the different MS.
Also the deliverables from WP5 with guidance on what to authorize, how to apply for authorization, definition of significant changes of processes as well as suitable teams for authorization will be important parts to integrate at the level of CA in the different MS.
Likewise the guidance on assessment of validations from the work of WP6 and the impact of clinical data from WP8, will have to be implemented at the CA level and included in the customized tool-box for the different MS.
Most likely it will be necessary to define a minimal requirement at the CA level and maybe rate the suggested recommendations from basic/acceptable to a desired level. We have to take into account that some MS already have working processes for authorization and licencing of new methods (at least in some areas in this sector) whereas others do not. Thus, the plan for implementation will be created as a ladder where the CA can introduce the recommendations/ requirements stepwise which will facilitate adjustments also at the CA level.

At the professional level:
An important part in implementation and sustainability of requirements and recommendations is to obtain consensus at the professional level. The results of the JA should be accepted by the professionals, preferably through international organisations (EBA, ESHRE, EATB, EEBA JAICE etc). These organisations are included as collaborating partners in WP6. WP8, with focus on clinical data as part of the authorization will have the output from other projects as a basis (VISTART, EuroGTP and ECCTR) where professional organisations have participated. WP4 suggest that the deliverables from WP6 and WP8 should be presented at the European meetings held by these associations, also described in the dissemination plan by WP2.
In this WP, the National Tissue Council (within the Swedish Association of Local Authorities and Regions) will be collaborating partners. The Tissue Council have working groups for Blood, ART, HPC and one for each regenerative tissue and one of their tasks is to provide guidance to tissue establishments. Thus, their role as collaborative partners will be to provide expertise and evaluate the recommendations and added value of the results from the JA and provide recommendations to the tissue establishments at the national level.

Work plan

Task 4.1 A pilot for integration of PPA in national policies in SE

In Sweden, it is the National Board of Health and Welfare (Socialstyrelsen) that is the regulatory CA transposing the Swedish laws on Blood safety and Quality and safety for tissues and cells respectively into regulatory acts. Thus, these acts regulate what should be done whereas IVO has the mandate to write regulatory acts on how it should be

Work Package 5: Development of Overall Guidance on organization of PPA system

Start month: 2
End month: 32
Work Package Leader: HPRA

This WP will develop guidance on how a Preparation Process Authorisation programme should or could be organised. This WP will take advantage of the results of the VISTART Joint Action as far as analysis of existing procedures and drafting of authorisation principles for novel processes is concerned, as well as the outcomes of the EUSTITE, EUROGTPII and ECCTR projects, that should however be extended to the blood sector. In order to ensure comprehensive consideration and review of VISTART WP5B, EUROGTP II and ECCTR outputs and to ensure that development of the relevant technical annexes and guidelines, leaders of these projects/actions/WP will be involved in two devoted meetings. Revision of guidance for blood establishments will be as well ensured by adhoc subgroup.
Lessons learned from experience in the systems for authorisation of medicinal products and medical devices at national and EU level will be examined and compared with existing experience in the TCB fields.
The following activities will be included:
- Development, circulation and analysis of results of a questionnaire survey of MS to explore and have a comprehensive picture of existing PPA systems – supplementing the VISTART WP5 Part B survey.
- Desk-based review of product authorisation systems in place in other relevant sectors (e.g. medicines, medical devices)
- Organization of a multi-country workshop to further explore organizational and procedural models identified by the survey and to identify strengths, weaknesses and best practices.
- Development of general good practice guidelines for PPA – putting a system and Standard Operating Procedures in place at the Member State level, including a methodology to inform blood and tissue establishments (BE/TE) regarding those procedures.
The guidelines shall include:
• An overview of the single authorisation steps from the request submitted by a BE/TE to the release of authorisation by CA
• Timing of application for PPA
• Definition of significant change in preparation process
• Terms for application (also building on the outcomes of VISTART WP6 - manual

for inspections)
• Organisational models and mandates of the CAs responsible for the PPA
• Optimal composition of the assessing team in the CA (members' qualifications, background, use of external experts etc.), definition of inspectors' involvement,
• Definition of types of authorisation (e.g. full, conditional, temporary – taking into account the outcomes of VISTART WP5 part B)
• Recommendations on how to analyse and address ethical issues.
• Development of model template forms for PPA.

Task 5.1 Review and revision of the outcomes of EUSTITE, VISTART WP5B, EUROGTPII and ECCTR projects results
Revision of the results of VISTART WP5B, EUROGTP II and ECCTR projects related to the authorisation of preparation processes for tissues and cells, so as to be applicable to blood establishments.

Task 5.2 Survey
Design a survey to review the implementation of the outputs from the previous projects and to have a comprehensive overview of the PPA systems in place in each of the Member States.

Task 5.3 Desk-based review of existing PPA systems in place in other relevant sectors

Task 5.4 Multi-country workshop
This workshop will have the objective of further exploring the different organisational models for PPA used by the various Member States and also to identify the associated common best practices.

Task 5.5 Development of Good Practice Guidelines for PPA
Elaborate good practice guidelines for PPA based on the requirements defined by the European Directives, analysis of the outputs of previous projects and the review and analysis conducted as part of this work package, in order to define a common approach and methodology.

Work Package 6: Technical Annex 1 to overall guidance: authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution* (including labelling and package inserts)

Start month: 1
End month: 30
Work Package Leader: NBC

This WP will be led by the National Blood Centre of Lithuania (NBC)
The WP leader will be supported by experts from two other partners from Lithuania, the LUHS Kaunas Clinic and the Santaros Clinic. This team will monitor the progress of the WP6 transversally and vertically, establishing communication with other partners and the co-ordinators of the Joint Action.
Regarding the general organization of the WP this work package will deal with two issues:
Part 1: Definition of the critical characteristics/properties (criteria) for each category of blood component, tissue or cell type (referring to EU blood legislation 2004/33/EC, EDQM blood component monographs and Tissue & Cell guidance). Examples of characteristics/properties might be the vitality of cells following processing, biomechanical strength parameters, a minimum volume, tissue integrity, a minimum number of motile spermatozoa. Where such criteria have already been defined by others, particularly for blood components, the group will review and build on established standards.
Part 2: Guidance on the assessment of methods to demonstrate achievement/maintenance of the critical characteristics/properties for each category of SoHO, in particular where changes are proposed/implemented in one of the preparation steps. The guidance will take into account the degree of risk to the patient from the blood component or tissue and cell product based on parameters such as historical data, degree of change in processing or testing. Evidence will include published and laboratory studies conducted by the applying BE/TE criteria identified under Part One and used to determine the depth of validation needed e.g. when the new process has been validated elsewhere, compared to cases where the new process has not been validated before. For reproductive T&C, the validation will take into account long term results regarding the health of the newborn baby. The methods proposed for the demonstration of compliance with the criteria could include in vitro validation studies or in-process verification steps.
The work of Part I will be developed by the organization of three (3) technical meetings for each sub-group. Meetings are going to be held at the same time and place and working groups will work in parallel sessions. During the technical meetings (M 3, M 8, M 13) the working group will determine and further elaborate the scope of characteristics/properties criteria, evaluate existing criteria and methodology, review the existing variety of examples, published studies, etc.
The work of Part II will be developed by the organization of three (3) technical meetings for each sub-group (M18, M.22, M.25). During the technical meetings the working group will study of the depth validation needed, identifying the cases when validation is applicable to the new process; evaluate the draft guidance of the characteristics/properties criteria for each category of blood component, tissues and cells, especially considering proposed changes implementation.
At M27 the closing technical meeting with participants of Part 1 and 2 will take place to agree on the last amendments needed in the definitive version of the guidance documents.
Finally as associated partner in this WP and to achieve at best WP9 objectives, PEI will work in parallel in this WP in order to build a data model of information on preparation processes (authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts).

Work Package 7: Technical Annex 2 to overall guidance: assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA

Start month: 2
End month: 26
Work Package Leader: ABM

this WP will be co-lead by ABM, France and FIMEA, Finland

The work will be developed by teleconferences, emails and during four technical meetings.
During the 1st technical meeting (M2) the working group will be split in subgroups in relation to different tasks (see below) and will define the general methodological approach.
During the further three technical meetings (M8, M14, M20), the working group will focus on the following topics/chapters of the technical annex:
Assessing and authorising methods related to donor testing, microbial inactivation, microbial status of final products;
Requirements for selection, validation and performance of donor infectious marker testing kits and other methods;
Requirements and criteria for laboratories performing donor testing;
Criteria for validation of microbial inactivation steps;
Criteria for validation of sterilisation processes.
Concerning the division of tasks between involved WP leaders and partners:
o ABM will be in charge of the ART field.
o FIMEA will be in charge of the blood field.
o For the Tissue&Cells field: ABM will be in charge of the HSC part, FIMEA of the other Tissues&Cells part.
At M25-26, the 4th final technical meeting will take place in order to agree on the last amendments needed in the definitive version of the deliverable.
Finally as associated partner in this WP and to achieve at best WP9 objectives, PEI will work in parallel in this WP in order to build a data model of information on testing procedures (assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA).

Work Package 8: Technical Annex 3 to overall guidance: assessing clinical data as part of PPA authorisation

Start month: 1

End month: 30
Work Package Leader: FIMEA

Part A)
(1) Specification of a set 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 manufacturing and testing protocols (6 months)
(2) Specification of appropriate risk-assessment models taking into account cumulative and aggregative risk assessment (1.5 months)
(3) Specification of criteria, appropriate to define "innovation" in manufacturing and testing protocols for human blood, cell, and tissue therapeutics taking into account the output of work package 5b of VISTART (1.5 months)
(4) Specification of a 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 manufacturing and testing protocols for human blood, cell, and tissue therapeutics (6 months)
(5) Review of data set by experts and stakeholders for completeness and relevance (3 months)

Part B)
(6) Setting up tools for data compilation (2 months)
(7) Proof of concept: data acquisition, evaluation of quality and validity of data (12 months)
(8) Definition of a methodological framework, appropriate to allow for an appropriate degree of harmonization as well as for an appropriate degree of flexibility, to evaluate quality and safety of human blood, cell, and tissue therapeutics based on clinical outcome data requested for authorization processes upon introduction of innovation to the current manufacturing and testing protocols for human blood, cell, and tissue therapeutics (12 months in parallel to 6 / 7)

Teleconferences, e-mails and five technical meeting will be carried out. During the first technical meeting (M2) practical working plan will be discussed and responsibilities agreed. Second, third and fourth technical meetings will be held at M8, M11 and M23 to finalise D8.1, D8.2 and D8.3 and a fourth technical meeting at M31 to finalise D8.4.

As an associated partner in this WP and to achieve at best WP9 objectives, PEI will work in this WP in order to build a data model of 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.

Work Package 9: Knowledge sharing on PPA between EU CAs

Start month: 12

End month: 36
Work Package Leader: PEI

From a methodological point of view the work will be performed in three blocks:
A) Building on the data models set up in WP 6, 7, 8, these data models will be integrated into a structure that will display the dependencies of 1) preparation methods, preparation steps, in-process controls and related results, 2) testing methods, results and specifications of the final product, 3) clinical outcome data demonstrating efficacy and safety of the product upon application to a patient
B) Building the framework for an electronically supported authorization process based on the integrated data model: Identification and evaluation of checkpoints critical to approval of blood, cells and tissues
C) Development of the concept of a platform to implement A, B. Part A, B and C will be developed in parallel. Part A covers the building on the data models set up in WP 6, 7, 8. The activities will be developed as follows and according to the indicated timeline:
IT security and data privacy concepts, data access concepts (3 months)
Organization and Structure of the electronically usable criteria catalogues and of the platform (3 months)
Architecture design for criteria catalogue and platform based on international standardization efforts and previously derived requirements: architecture model, description of data exchange/integration and security components (e.g. identification and authentication, Authorization, Logging, pseudonymization and anonymisation) (6 months)
Aggregation of the data structures of the data sets on authorised preparation processes, testing methodologies and clinical outcome criteria to a common domain model and specification of data structures and data semantic using existing standards as a technical representation of the domain model (12 month)

Work Package 10: Training courses and manual for training

Start month: 20
End month: 36
Work Package Leader: KCBTiK

The work of WP10 is strictly connected to the final results of the WP5, WP6, WP7, WP8 and WP9,
This WP will be led by the KCBTiK, a budgetary unit submitted to the Polish Ministry of Health, which tasks include the supervision and inspection of tissue and cell banks in Poland as well as the organisation of training courses on the recovery, collection, testing, processing, sterilization, storage and distribution of tissues and cells.
Task 1: design of training course.
Considering how extensive will be deliverables provided by the above-mentioned WPs, in the second part of the project two technical meetings will be convened by

the WP leader. During the first technical meeting of WP10 (M20) the working group will agree on the design of the face-to-face training course contents: training materials incl. examples, case studies etc. After the first face-to-face training course, a summary will be provided by tutors with practical details and prepare the issues concerning a manual content will be discussed as well. At M35 the closing technical meeting will take place to agree on the last amendments needed to the definitive version of manual.

Task 2: face-to-face training

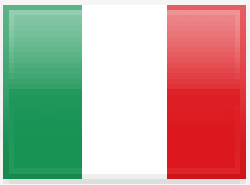
The face-to-face training courses will take place at M30 and M33 and each of them will last 2 full days at least, including theoretical and practical training. The arrival of participant shall be planned a day before the beginning of the course and their departure shall be planned the day after the ending of the course. The training courses will be organised in Poland and all the EU CA from both blood and tissue and cells fields will be invited to attend it.

Task 3: Manual for training CA inspectors

The training course designed and held in this work package will be documented. All materials such as lectures, examples, case studies will be used as the basis for the preparation of the Deliverable 10.1 “Manual for training CA inspectors that assess and authorize preparation processes of tissue, cell, and blood products”. The manual will be made available at M36 to all Blood, Tissue and Cell Competent Authorities in electronic version downloadable from project website and from ECAS, so that they can use them for national or regional inspector training in the future.

COORDINATOR, LEADER CONTACT AND PARTNERS

COORDINATOR



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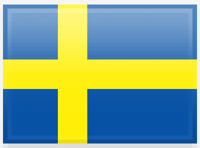

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Country: Sweden
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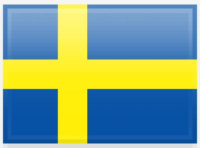
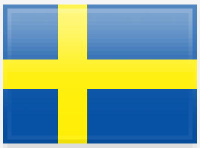


Health and Social Care Inspectorate (IVO)
Street: SULVAGEN 41
City: STOCKHOLM

Country: Sweden
Website: http://www.iss.it



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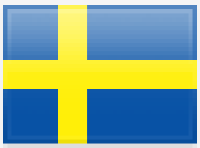

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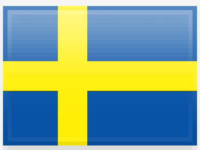

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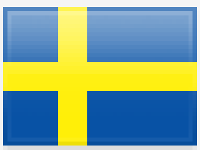

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HEALTH PRODUCTS REGULATORY AUTHORITY
Street: Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace
City: Dublin 2

Country: Ireland
Website: http://www.iss.it

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SERVEI CATALA DE LA SALUT
Street: Gerencia de Serveis Assistencials Travessera de Les Corts 131-159 Edifici Olimpia
City: 08028 Barcelona

Country: Spain
Website: http://www.iss.it

SERVEI CATALA DE LA SALUT
Street: Gerencia de Serveis Assistencials Travessera de Les Corts 131-159 Edifici Olimpia
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Country: Spain
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VIESOJI ISTIAGA NACIONALINIS KRAUJO CENTRAS
Street: Žolyno g. 34
City: LT-10210 Vilnius

Country: Lithuania
Website: http://www.iss.it

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
Street: Buckingham Palace Road

City: SW1W9SZ London

Country: United Kingdom
Website: http://www.iss.it

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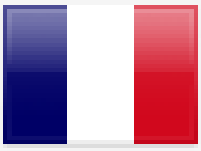
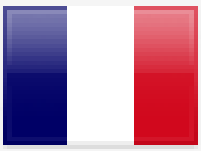


Agence de la biomédecine
Street: 1 avenue du Stade de France
City: 93212 Saint- Denis La Plaine

CEDEX CEDEX
Country: France
Website: http://www.iss.it



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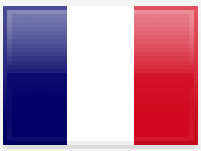

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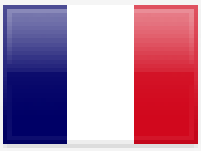

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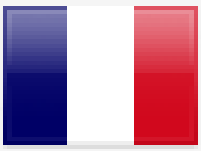

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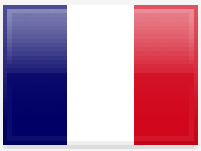

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LAAKEALAN TURVALLISUUS-JA KEHITTAMISKESKUS
Street: Microkatu 1
City: 70210 Kuopio
P.O. Box 55 00034 FI
Country: Finland
Website: http://www.iss.it

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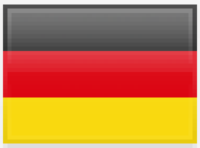
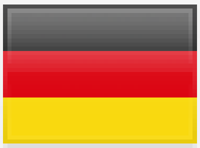


BUNDESINSTITUT FUR IMPFSTOFFE UND BIOMEDIZINISCHE ARZNEIMITTEL
Street: PAUL-EHRLICH-STRASSE 51-59
City: 63225 LANGEN

Country: Germany
Website: http://www.iss.it



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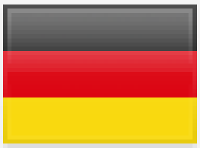

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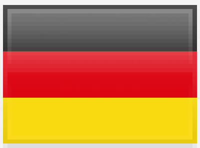

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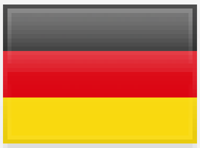

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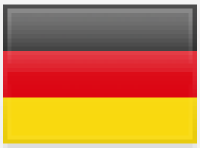

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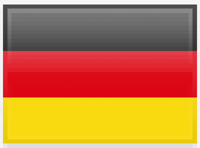

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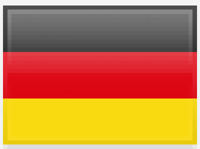

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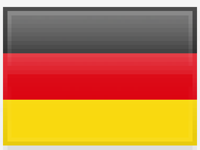

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BANC DE SANG I TEIXITS
Street: Passeig Taulat 116
City: 08005 BARCELONA

Country: Spain

Website: http://www.iss.it

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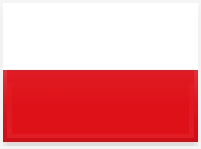

KRAJOWE CENTRUM BANKOWANIA TKANEK I KOMOREK
Street: Chałubińskiego 5
City: 02-004 Warszawa

Country: Poland
Website: http://www.iss.it

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HUMAN TISSUE AUTHORITY
Street: 151 Buckingham Palace Road
City: SW1W 9SZ London

Country: United Kingdom
Website: http://www.iss.it

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AGENTIA DE TRANSPLANT
Street: STRADA TESTEMITEANU 29
City: 2025 CHISINAU

Country: Moldova
Website: http://www.iss.it

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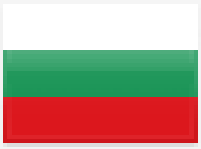
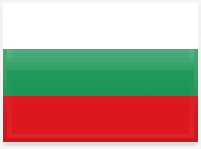


EXECUTIVE AGENCY FOR TRANSPLANTATION
Street: Bratja Miladinovi 112
City: 1202 Sofia

Country: Bulgaria
Website: http://www.iss.it



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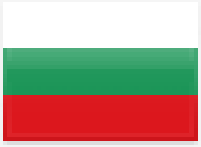

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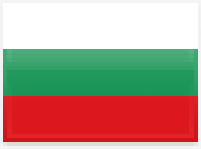
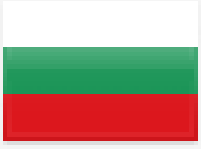


EXECUTIVE AGENCY 'MEDICAL SUPERVISION'
Street: 3, 'Sv. Georgi Sofiiski' Str.
City: 1606 Sofia

Country: Bulgaria
Website: http://www.iss.it



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Ministry of Health of the Republic of Cyprus
Street: 1 Prodromou Street & 17 Chilonos Street 1 & 17
City: 1448 Nicosia

Country: Cyprus
Website: http://www.iss.it

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Street: 1 Prodromou Street & 17 Chilonos Street 1 & 17
City: 1448 Nicosia

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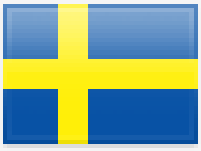
Medical Products Agency
Street: DAG HAMMARSKJOLDS VAG 42
City: 751 03 UPPSALA

Country: Sweden
Website: http://www.iss.it



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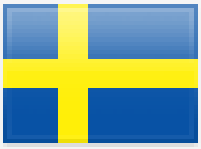

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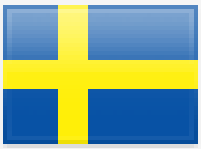

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ASOCIACION ESPAÑOLA DE BANCOS DE TEJIDOS
Street: Avenida de las Xubias, s/n
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SERVICIO ANDALUZ DE SALUD
Street: Avenida de la Constitución 18
City: 41071 SEVILLA

Country: Spain
Website: http://www.iss.it

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LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS
Street: Eiveniu 2
City: 50009 Kaunas

Country: Lithuania
Website: http://www.iss.it

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Street: Eiveniu 2
City: 50009 Kaunas

Country: Lithuania
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VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS
Street: SANTARISKIU G 2
City: 08661 VILNIUS

Country: Lithuania
Website: http://www.iss.it

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Street: SANTARISKIU G 2
City: 08661 VILNIUS

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Website: http://www.iss.it

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KLINIKOS
Street: SANTARISKIU G 2
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Country: Lithuania
Website: http://www.iss.it

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Third Newsletter

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 13/01/2021
Third newsletter of GAPP action

Second Newsletter

7TH HRC
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 15/07/2020
second newsletter of GAPP action

newsletter

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 14/03/2019
Each newsletter will provide an overall picture of the improvements of JA activities. there will be 4 newsletter at Month 9-18-27-36. To be produced and circulated in electronic version only.

MD4. Layman version of the final report

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 10/06/2022
This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group. To be produced and circulated in electronic version only.

Final technical and financial report

ISS-CNT-CNS
facilitatinG the Authorisation of Preparation Process for blood and tissues and

cells (GAPP)
Published on: 10/06/2022
This report describes the project implementation, problems encountered and the results achieved. Relevant milestones will be annexed to the report.

Final Dissemination and Communication report

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 10/06/2022
This document is meant to provide a detailed list of dissemination activities conducted by Associated and collaborating partners in their countries.

Recommendations for integration in national/regional /local policies

IVO
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 10/06/2022
This deliverable will provide useful recommendation for the integration in national/regional /local policies of GAPP guide, annexes, knowledge platform and training courses

Multi-stakeholder Conference

7TH HRC
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 11/03/2022
Final dissemination conference

Final evaluation report

MOH - HR
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 11/03/2022
produced on the basis of continuous evaluation and outputs during project. This docuement will collect also the opinion of the EAB on the final outcomes of the action.

Operating Concept of a platform to implement A, B

PEI

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 23/02/2022

Operating concept of platform eligible to serve as a template for technical realization of A and B within an electronic tool

MD6. Report on the integration in national policies and sustainability

IVO

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 11/02/2022

This report will highlight the integration of project outcomes in national policies and their possible sustainability

Manual for training CA inspectors for accessing and authorise PP of BTC product

KCBTiK

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 11/02/2022

Manual for training Competent Authorities inspectors that assess and authorise preparation processes of tissue, cell, and blood products

Good practice guideline to authorisation on preparation processes in blood, tissues and cells

HPRA

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 01/12/2021

This documents will collect the good practices to authorisation on preparation processes in blood, tissues and cells

Deployment of updated version of blood risk assessment tool

BST
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 01/12/2021
Release of updated version of risk assessment tool for blood professionals

Risk assessment Guide

BST
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 01/12/2021
Update version of EUROGTP-II risk assessment Guide including blood chapter.

Technical Annex on authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution

NBC
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 12/10/2021
This deliverable will be the annex I of the Guide. The document will be focused on authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution. It will be divided into 3 parts (Blood, tissues, cells and reproductive tissues and cells).

Framework for an electronically supported authorisation process

PEI
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 30/08/2021
definition of a framework for an electronically supported authorisation process

Report on the integration at one national level - a pilot in SE

IVO
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 17/08/2021
Report on the integration at one national level – a pilot in Sweden

Data model of information on clinical outcome of application of human blood, cell, and tissue therapeutics

BST
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 25/05/2021
Data model of information on clinical outcome of application of human blood, cell, and tissue therapeutics

Technical annex on assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA.

ABM
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 23/02/2021
Technical annex on assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA.

Extension of the outputs of previous projects, VISTART WP5B, EUROGTP II etc., to be applicable to blood establishments

CatSalut
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 25/11/2020

Analysis of previous projects outputs

Report on the outcome and conclusions of the survey, the deskbased review of PPA in other fields and the multi-country workshop

CatSalut
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 25/11/2020
Report with the conclusions of the survey on present situation, Desk-based review of existing PPA systems in place in other relevant sectors, and working document for the multi-country workshop

Methodological framework to evaluate quality and safety of human blood, cell, and tissue therapeutics based on clinical outcome data requested for authorisation processes upon introduction of innovation to the current processing and testing protocols

BST
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 08/10/2020
Methodological framework to evaluate quality and safety of human blood, cell, and tissue therapeutics based on clinical outcome data requested for authorization processes upon introduction of innovation to the current processing and testing protocols for human blood, cell, and tissue therapeutics

Integrated data model

PEI
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 08/10/2020
Technical concept of platform

Progress Technical and Financial Periodic Report

ISS-CNT-CNS
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 17/07/2020
This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes. This document covers the period from M1 to M18

Intermediate evaluation report

MOH - HR
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 18/12/2019
produced on the basis of continuous evaluation of activities and outputs during evaluation period. This docuement will collect also the opinion of the EAB on the intermediate outcomes of the action.

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, an

FIMEA
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 18/12/2019
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

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

FIMEA
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 29/10/2019
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

Dissemination & Communication Strategic Plan

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 25/01/2019
The dissemination plan of the Joint Action will provide a roadmap for all JA dissemination activities.

Financial manual

ISS-CNT-CNS
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 12/12/2018
The manual will provide the associated partners all the relevant information related to the managment of project funding, the use of the IT portal and the submission of financial statement on the the same portal

MD3: Leaflet

PGH
facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)
Published on: 12/12/2018
A leaflet to promote the project must be produced at the beginning.

MD5. Web-site

PGH

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 12/12/2018

Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the applicants. In the private area will be uploaded all the docuements classified as Confidential

Final evaluation plan, including setting up of EAB

MOH - HR

facilitatinG the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

Published on: 12/12/2018

description of the evaluation system