ARTHIQS

Assisted Reproductive Technologies & Haematopoietic stem cells
Improvements for Quality & Safety throughout Europe

Newsletter

December 2015

ARTHIQS – Assisted Reproductive Technologies and Haematopoietic stem cells Improvements for Quality and Safety throughout Europe – is a 3 year European Joint Action funded by the European Commission under the 2008-13 Health Programme, dealing with Assisted Reproductive Technologies and Haematopoietic Stem Cells for Transplantations. ARTHIQS consortium is gathering 15 partners and 9 collaborators from 18 different Member States and is coordinated by the Agence de la biomédecine in France.

Those two fields, although deeply different in practices and needs were gathered together since both involve living cell donors and recipients, and fall under the 2004/23 EUTCD (European Union Tissues and Cells Directive) regulation which requires ensuring their protection.

The idea of this project arose from the fact that nowadays Assisted Reproductive Technologies show both public and private diverse practices within and between Member States. These disparities are notably enhanced by the fact that a significant number of countries seek to have a dedicated and trained Competent Authority or a Delegated Body such as a medical organization, providing expertise, controlling information to be provided to donors and beneficiaries, ensuring that practices are following quality and safety criteria for donors and beneficiaries (selection, consent, access to fertility preservation, registries, vigilance system *etc.*).

Photos referring to ART facilities and processes (Photos Benoit Rajau for the Agence de la biomédecine)

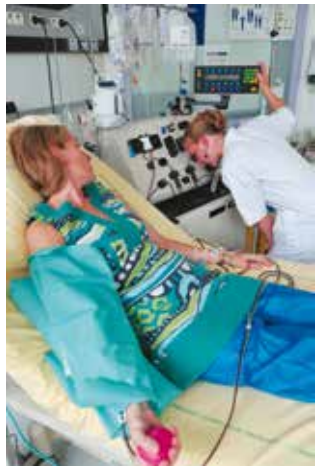
Regarding Assisted Reproductive Technologies, ARTHIQS will therefore provide: i) institutional guidelines for those key aspects and regulation in Assisted Reproductive Technologies, ii) Assisted Reproductive Technologies -specific knowledge in each Member State and so providing support to the setting or the strengthening of more specific national organisations, and iii) the specific information and training to Assisted Reproductive Technologies centre inspectors.

The other topic targeted by the ARTHIQS is Haematopoietic Stem Cells for Transplantation.

Despite the establishment of large registries of volunteer donors (for bone marrow and Peripheral Blood Stem Cells) and banks of cord blood, finding unrelated compatible donors continues to be difficult. Facing the growing number of patients to be transplanted, it is of utmost importance to facilitate a secure, efficient and equal access to Haematopoietic Stem Cells for Transplantation from unrelated compatible donors to patients. At the same time, the development of Haematopoietic Stem Cells sources (mobilized peripheral Haematopoietic Stem Cells, cord blood) contributed to increase both the number and the age of patients receiving Haematopoietic Stem Cells transplants and modified medical practices.

However, across the European Union, Haematopoietic Stem Cells donor follow-up is widely recognized to be insufficient, especially regarding recipient-related donors.

Additionally, Cord Blood Banks rapidly evolved. For these banks to be authorized, generic EU inspection guidelines following the EUTCD requirement exist, but would be worthwhile developing and updating in accordance to the specific technical requirements of Cord Blood Banks, keeping in mind that one of the main goals should be the safety of future recipients.



Peripheral Blood Stem cell Collection (left) and Cord blood collection (right), tests, quality criteria, storage; both under strict quality and safety criteria (Photos Benoit Rajau for the Agence de la biomédecine).

Therefore, ARTHIQS also aims to develop guidelines regarding the regulation of Haematopoietic Stem Cells for Transplantation dealing with the main characteristics for Haematopoietic Stem Cells donor follow-up registries to be implemented both locally and nationally, and guidelines for cord blood banking *i.e.* covering all stages and including the minimum requirements for authorising/re-authorising Cord Blood Banks and the minimum quality and safety standards for Cord Blood Banks, regardless of their status and purpose (allogeneic/autologous, public/private), drafted along with guidelines for Cord Blood Banks inspectors.

The recommendations concerning the set-up of a Haematopoietic Stem Cells donor follow-up registry will set the basic framework for establishing registries as a tool for the upgrade/improvement of safety in Haematopoietic Stem Cells donation. The main outcome of the guidelines for Cord Blood Banks will be the establishment of EU common good practice in the field. Overall outcome will be a significant increase in quality and safety practices in cord blood banking, and Competent Authorities/ Delegated bodies having tools to assess the compliance of their Cord Blood Banks thanks to the guidelines generated. This last part of the work is also aiming at broader and safer Haematopoietic Stem Cells availabilities for patients in the need of a Haematopoietic Stem Cells transplant (providing that the use of cord blood is suitable), since it is the matter of transplanting the right patient at the right time with the right Haematopoietic Stem Cells source (bone marrow, Cord blood, peripheral Haematopoietic Stem Cells).

Peripheral Blood Stem Cells, tests, quality criteria, storage (Photos Benoit Rajau for the Agence de la biomédecine).

OBJECTIVES

ARTHIQS aims to develop guidelines for key aspects of Assisted Reproductive Technologies and Haematopoietic Stem Cells Transplantations regulations by complementing and developing requirements for safety and quality to the benefit of both Donors and Recipients.
Concretely, ARTHIQS objective is to provide Member States with tools to address current growing concerns of both fields and to improve the overall harmonisation of regulations.

ART process (Photos Benoit Rajau for the Agence de la biomédecine).

Concerning Assisted Reproductive Technologies (ART), ARTHIQS is aiming at strengthening and building-up know-how to set an institutional and organisational framework at the Competent Authority / Ministry of Health / and delegated bodies (Medical Agencies) levels in each of the 28 Member States; hence enhancing gamete donors and Assisted Reproductive Technologies beneficiaries' safety throughout the EU.

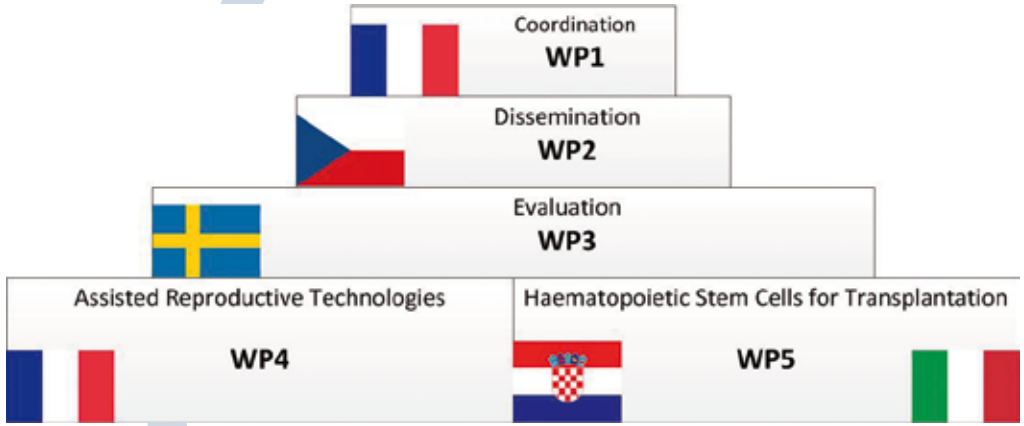
Regarding Haematopoietic Stem Cells Transplantations (HSCT), ARTHIQS focuses on increasing donors and recipients' safety by enhancing standards of Haematopoietic Stem Cells donation, notably through donors' follow-up registry.
As a complement, since this part of the work also includes the drafting of a Guideline for Cord Blood Banking that entails the minimum quality and safety requirements for authorising/re-authorising Cord Blood Banks, along with guidelines (Vade–Mecum and a Curriculum) for Cord Blood Banks inspectors.

Cord Blood Bank, storage area (Photos Benoit Rajau for the Agence de la biomédecine).

Professionals of both fields are also clearly targeted by ARTHIQS since Tissue Establishments *i.e.* Assisted Reproductive Technologies centre and Cord Blood Banks that are expected to comply with guidelines and also professionals providing medical care to the Haematopoietic Stem Cells donors will have to be involved as well in the setting-up of Haematopoietic Stem Cells donors' follow-up registry.

PROJECT ORGANISATION

ARTHIQS structure and organisation follows the standards of projects and Joint Actions co-funded by the European Commission: three horizontal work packages (Coordination, Dissemination and Evaluation) and technical work packages dealing with the more specific medical and scientific activities.



ARTHIQS work and responsibilities are divided in sections designated as work packages (WPs), the horizontal WPs are: Coordination (France: Agence de la biomédecine, delegated body for Assisted Reproductive Technologies and Haematopoietic Stem Cells), Dissemination (led by Czech Republic; SUKL- Assisted Reproductive Technologies delegated body) and Evaluation (led by Sweden: IVO- The Health and Social Care Inspectorate, Competent Authority). So as to ease the management of ARTHIQS, technical (medical and scientific) work packages were simply divided in two sections corresponding with those 2 fields: WP4 dealing with Assisted Reproductive Technologies and led by France (Agence de la biomédecine) and the WP5 on Haematopoietic Stem Cells for Transplantation co-led by the Competent Authority of Croatia - The Ministry of Health and Italy - ISS Centro Nationale di Trapianti (public technical and scientific body).

WP1: COORDINATION

Leader: Agence de la biomédecine, France

ARTHIQS coordinator has to notably manage, organise and channel the overall Joint Action, and make sure that the work is executed as planned. Hence permanently exchanges information on progress, troubleshooting, deliverables produced and results achieved, meets with all Work Packages (WP) leaders at the end of each meeting to assess meeting efficiency and propose modification and actions when necessary. Importantly, the coordinator also has to ensure the quality of generated guidelines and outcomes at large.

WP2: DISSEMINATION

Leader: State Institute for Drug Control, Czech Republic

With the launch of the ARTHIQS Joint Action, the WP2 Team started to work on branding and first proposals of the project logo and graphic manual were discussed during the kick-off meeting. Following adoption of ARTHIQS logo in June 2014, WP2 concentrated on creation of the website www.arthiqs.eu, one of WP2 key deliverables. The website was successfully launched on 15 September 2014 and represents one of the tools used for dissemination of information about the ARTHIQS aims and achievements to its stakeholders, ranging from members of the general public and patient organisations to healthcare professionals, health institutions, decision makers and National Competent Authorities.

The website is designed to be easy to navigate and provides the stakeholders with a user-friendly portal to keep them up to date on progresses. The private part of the website serves as a communication channel for project partners where all important documents are shared. Continuous update of the website keeps all partners informed on important news, meetings and events that take place in the project or are planned in the near future. State Institute for Drug Control (SÚKL) as leader of WP 2 will continue to administrate the website five years after the project´s completion.

Month record - July 2015 – 1201 visits/month

Information about ARTHIQS will reach its target audience also through printed materials which include the project brochure and newsletter. At the beginning of 2015, 2500 printed brochures were distributed among the project participants. WP 2 leaders performed a short survey about national dissemination activities of individual associated and collaborating partners with the following 5 questions:

- Do you have any information about the project on your website?
- Where did you distribute brochures of the project or where you are going to distribute them?
- Did you publish any press release or other kind of articles about the project (newspapers, scientific magazines *etc.*)?
- Did you perform any other activity connected to dissemination of information about the project like conferences, fairs, open days *etc.*?
- Did you prepare any presentation about the project?

Most national activities were aimed at hospitals, universities, centres of ART, competent authorities for HSC and healthcare professionals (scientific societies, conferences, training events). Other partners of the project distributed brochures on courses and to general public or universities and healthcare institutions involved in biomedicine (i.e. blood establishments, ART centres, tissue establishments and haematopoietic stem cells collection sites). In total, 2160 brochures were already distributed by all project partners.

The remaining brochures will be distributed during the project with the newsletter, another WP2 deliverable aimed at both professional and lay public.

All WP leaders of the project maintain regular communication via e-mail and phone conferences and the dissemination of information inside the project takes places through e-mail or internal website of the project that is used as a repository for documents created during the project. This repository provides an important means for sharing progress between work package leaders, active partners and the coordinating partner. When completed, the final documents will be published on the public site and sent to all stakeholders.

Through the collaboration with all partners it will be possible to monitor and support all dissemination activities that will take place at national level and give them appropriate visibility on the project website. SÚKL and other partners of the project will ensure that all deliverables produced by ARTHIQS reach not only the relevant target groups, but also any stakeholder of the domains that might contribute to pass on its conclusions wherever it can be useful, in accordance with the time frame and dissemination levels defined for given information. Indeed, WP 2 leaders also have to undertake actions to ensure that the results and deliverables of the project will be made available to the target groups.

WP3: EVALUATION OF THE PROJECT

Health and Social Care Inspectorate

Leader: Health and Social Care Inspectorate (IVO)

The general objective of this WP is to keep the project **"move forward but stay on the road".**

For this, several indicators that are to be evaluated have been formulated to verify if the project is being implemented as planned and reaches the objectives.

Swedish Association of Local Authorities and Regions

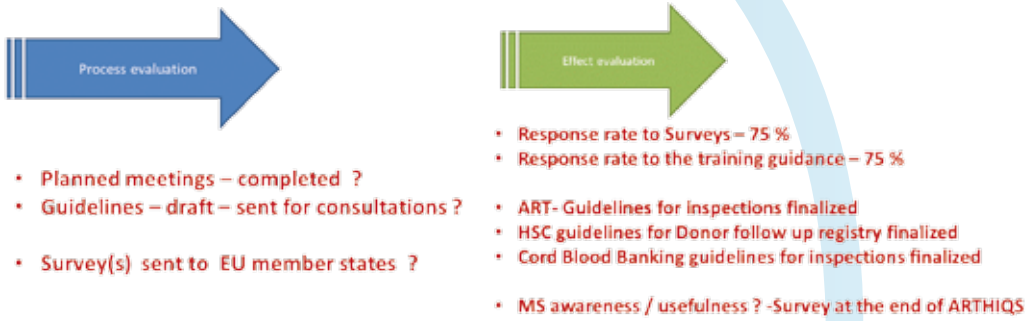
Together with collaborators from the National Tissue Council (hosted by SALAR) the WP will evaluate:

- The progress of the work (progress indicators)
- The output of the milestones in each WP (output indicators) and
- The outcome and impact of the project (outcome indicators).

Each of the indicators is connected to the **specific objectives** of ARTHIQS and the evaluation will contribute to improve the efficiency and quality of the Joint Action.

Since the ARTHIQS Joint Action is merging two different fields, evaluation of Assisted Reproductive Technologies and Haematopoietic Stem Cells dedicated sections, documents and tools to be generated must be done separately. Accordingly different experts who will act as medical/scientific counsellors to WP3 - Evaluation leader, especially for deliverables, will be mobilized. The overall progress evaluation of the project by the WP3 - Evaluation leader will be continuous through project meetings attendance, a 6 month period WP4- Assisted Reproductive Technologies and WP5 - Haematopoietic Stem Cells accomplishments check list (compared to the working plan) and clarification for deviations, feedback from the different evaluation experts mobilized on WP4 - Assisted Reproductive Technologies and WP5 - Haematopoietic Stem Cells achievements.

The interim Evaluation report will therefore include achievement assessments and quality evaluation reviews.



One additional key element for an independent evaluation of ARTHIQS is the participation of an independent External Advisory Board (EAB), who was designated by the Coordination. The EAB will participate to 2 meetings, review WP4- Assisted Reproductive Technologies and WP5- Haematopoietic Stem Cells deliverables, and contribute to the improvement of ARTHIQS outcomes through comments, suggestions and recommendations.

Evaluation of project outputs and outcomes are, as ever, trickier. One way to get some hindsight on ARTHIQS accomplishment is to have all work finished a while before the official end of the project. This is why it has been designed with technical sections WP4- Assisted Reproductive Technologies and WP5- Haematopoietic Stem Cells ending up at M30. WP3- Evaluation leader will then send a brief questionnaire to selected stakeholders who received ARTHIQS guidelines: Cord Blood Banks, CBB inspection Competent Authority, ART centre, ART inspection Competent Authorities /Ministry of Health, to assess if those documents were informative, helpful and used. Results from this brief analysis will be presented during final meeting and WP3- Evaluation report.

Evaluation will notably be performed through surveys and interviews.

A 6 month check list of the first achievements of the project that was done in December 2014: reflecting that indeed ARTHIQS web site was created, the first technical meeting with all WP- collaborators was held in Stockholm December 16, 2014. The draft for ART- Survey (WP4) sent to, commented and agreed on by all collaborators, the draft survey (WP5) for regarding donor follow-up registry was sent to, commented and agreed on by all collaborators.

The Milestones of WP3 until the end of 2015, as set up, are to establish an Evaluation plan. The plan consists of progress and output indicators for the proposals and until now, response rate (output indicator) of the respective surveys (WP4 and WP5) as a basis for development of guidelines have been successfully reached (> 70% response rate, ensuring a EU coverage large enough to reflect the situation in Member States). Furthermore, progress indicators (the preliminary draft for respective delivery was available to the participants) are reached.

Specific objective 1	Design of a proposal (guidelines), endorsed by all partners and acceptable in all Member States, for an Assisted Reproductive Technologies institutional and organisational system at national level	
Process indicators	**Output Indicators**	**Output Indicators**
ART survey is approved and sent at M6	More than 70% of the addressees answer the ART survey	
Consensus on all items to be included in the guidelines at meeting 2 max	ART survey brings a precise knowledge of the ART landscape at the EU level regarding organization and regulation of practices in each MS	
Number of consensus positions found at each meetings on selected items	Feedback on ART guidelines is received at M34, comments are reviewed and relevant ones incorporated in the document	ART-dedicated Competant Authorities or delegated bodies are created or modified in accordance with guidelines
Guidelines sent out for consultation at M30	80% of feedbacks on ART guidelines rate the document useful/very useful	Level of implementation of European Directive for Tissues and Cells (EUTCD)
		Level of implementation of EUTCD increasing throughout European Union (based on annual EU implementation survey)

Example of Indicators concerning Assisted Reproductive Technologies

WP3- Evaluation is presently preparing an Interim Progress Analysis and Evaluation Report. This report focuses on progress of the project, difficulties and suggestions on improvements. In addition, WP3 will prepare a Final Evaluation of the Impact of the Deliveries that will be sent out to stakeholders at the end of the project.

WP4 : ASSISTED REPRODUCTIVE TECHNOLOGIES

agence de la biomédecine

Leader : Agency of Biomedicine, France

What is planned?

- Survey: to have the most complete view of the organization and institutional status in place within the EU and to assess the needs of ART Competent Authorities/Delegated Bodies in terms of capacity-functionality.
- Institutional guidelines: to develop institutional and organizational guidelines for the enhancement of an ART-specific expertise at official level in each MS, leading to a more appropriate and consistent level of national organisations.
- Inspection guidance: to develop a hand book (vade-mecum) for establishing a standardized and effective way of inspecting ART establishments, leading to a better controlled and monitored network. Also included a Curriculum – An inspector's profile.
- Training Course: to have ART-trained representatives at the CA level able to implement the EUTCD and to design future national plans. ART representatives/ inspectors from partner and non-partner CAs to be trained by the end of the action.

Where are we now?

Following the kick-off meeting where the outline of the activities was presented to participants, a questionnaire dedicated as a tool for implementing the survey on current institutional-organisational schemes was drafted. The questionnaire is divided into 7 sections: Legal Framework, Authorisation/Accreditation/Licensing, Inspection, Vigilance, Data collection and management, Communication, Policy development. Through an interaction with the participants, it was finalised and circulated within the WP countries in order to collect the data (November 2014). Preliminary results were analysed and discussed at the 1st Technical Meeting (end of 2014) where clarifications followed in order to better draft the report. An "extended survey" was designed in order to control the existence of the derived models in the other non-participating countries by asking them to select the scheme that fits best to their existing national organisation and to identify similarities/differences to those aspects described in the draft.

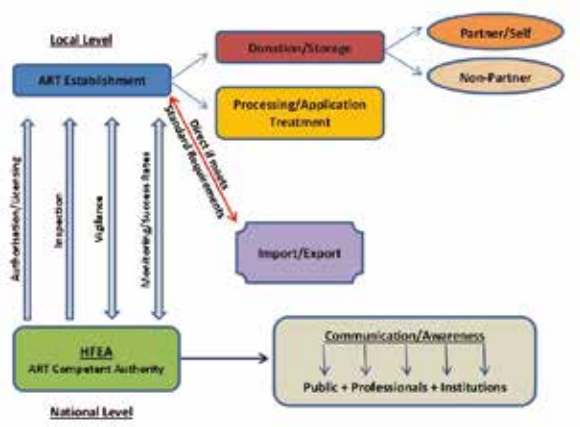
The final report (Deliverable 5) describes the findings of both surveys (amongst the WP members and extended to all MS), analyses the different organisational models, and provides additional information on each participating authority.

Organisational Models

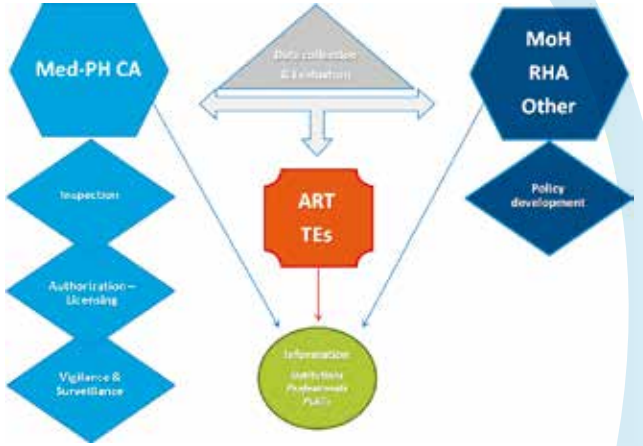
As reported in the Communication [EC COM(2009)708] on the application of Directive 2004/23/EC, "all Member States have designated a competent authority in accordance with this provision and in 21 Member States, the designated competent authority is responsible for all types of tissues and cells. France, Greece, Portugal, Finland and the

United Kingdom have a specific competent authority for reproductive tissues and cells."
The transposition and implementation of the EUTCD was based on the existing national regulations and organization of the health system. Where ART services had been well established, there were only some minor adjustments needed in order to implement the new requirements (i.e. FR and UK). In other cases the developments in ART regulation were in parallel with the EUTCD (i.e. PT, BG) and in some countries (i.e. MT and IT) the ART legislation has been developed or amended after the implementation of the EUTCD.
ART establishments are not simply banks of reproductive material but include also the sites of human application (Embryo transfer) and the majority of practices involve the use of partner's gametes for Artificial Insemination (AI) or in vitro fertilization (IVF), it is therefore necessary to acknowledge the substantial differences to the procedures that take place in the field of tissues and cells with a few exceptions (namely processing and banking).
In an attempt to compare the organizational models that have developed throughout European Member States we can identify some main characteristics, namely:

- The existence of an ART specific law that established the CA before the EUTCD
- The existence of a unique and autonomous national authority that is responsible for the authorization and control of ART establishments
- The ART Authority acts as a Delegated body of the MoH and holds the role of a technical/scientific consultant in collaboration with other Regional Health Authorities (RHA).
- The CA is the authority for Organs Tissues and Cells
- The CA is a general Health Authority
- Inspections that are performed by a general health inspectorate body in cooperation with the ART authority
- Different activities on the basis of legal permissions (embryo donation, non-partner gametes) that create different needs and responsibilities for the CA



Schematic representation of the ART organizational system in the UK



Schematic representation of the "Medicines - Public Health CA" Model
(Med-PH CA = Medicines - Public Health Competent Authority, MoH = Ministry of Health, RHA = Regional Health Authority, ART TEs = Assisted Reproduction Technologies Tissue Establishments)

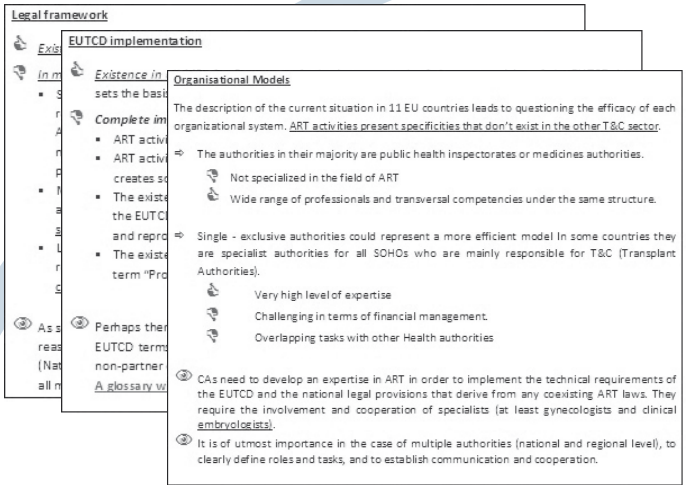
Extended Analysis

Following the analysis of the models that were identified within the working group participating countries, the second phase of the survey took place i.e. the extended analysis of the situation in all EU Member States.
The main scope of the second study was to identify the existence of these models (mapping), to verify their functionality (challenges) and to check if there could be any other different system that was not already described.

The results show that the predominant model in Europe (22 out of 28 MS that responded) is the "Medicines/Public Health Authority" (64%) and in most cases these CAs are responsible for the entire spectrum of Substances of human origin (SOHOs). This also means that reproductive tissue and cells are best considered as medicinal products of human origin, and ART establishments are considered tissue establishments responsible for collection/procurement, processing, storage and distribution (as laid down in the EUTCD).

MODEL	ARTHIQS	Other MS	Total
Exclusive ART Authority (All in one)	1	-	1
Exclusive ART Authority with shared missions	2	-	2
Exclusive SOHO Authority in collaboration with other National/Regional Authorities	3	2	5
Medicines / Public Health Authority	5	7	12
Other	-	2	2

Conclusions



Information gathered, helped in understanding the current status of each country, the similarities and divergences, regardless of the variety and complexity of legislations in force, identifying the actors, and highlighting the critical issues and challenges.
Conclusions and proposals are mainly focusing on three issues: the organisational models, the EUTCD implementation and the legal frameworks.

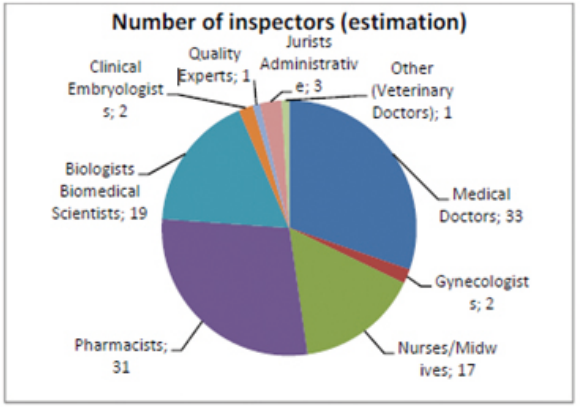
ART activities have been developing in all the EU countries within a highly heterogeneous legal framework. The critical difference between MS is the existence of ART legislation prior to the introduction of the EUTCD, meaning that those countries had a system already in place. The heterogeneity is evident also through the existence of different organizational systems.

The future steps

The issues that were highlighted in the survey report will be addressed in more detail in the Institutional Guidelines that the working group is currently preparing. Solutions will be provided for harmonizing the practices and enhancing the role and competencies of all relevant authorities.
These guidelines should be specifically targeted to ART public officials (managers, inspectors, vigilance experts etc.) and they will be addressing issues on quality & safety management, donor information, selection & consent, information to ART beneficiaries, access to fertility preservation). Additionally, they should provide tools to the institutions on how to address public concerns in ART sensitive issues.

By the end of 2015 a draft version of the inspection guide shall also be elaborated. Information collected through the survey has provided insight on the current situation regarding ART Centre inspectors' profile.

Professional background of Inspectors	
Medical Doctors	BG, CZ, FR, IT
Gynecologists	PT
Nurses/Midwives	BG, CY, SE, UK
Pharmacists	BE, FR, MT, SE
Biologists Biomedical Scientists	BE, BG, CY, CZ, IT, SE, UK
Clinical Embryologists	PT
Jurists/Administrative	BG, IT, PT
Quality Experts	IT
Other (Veterinary Doctors)	BE



In order to disseminate and familiarise with these two guidelines, a specific training meeting (workshop) will be organized in October 2016 with the aim to inform and qualify designated ART-dedicated responsible persons within the EU countries, thus creating a network of institutional representatives from each of the 28 MS.

WP5: HAEMATOPOIETIC STEM CELLS FOR TRANSPLANTATION

Ministry of Health
To Health. Together.
Centro Nazionale Trapianti

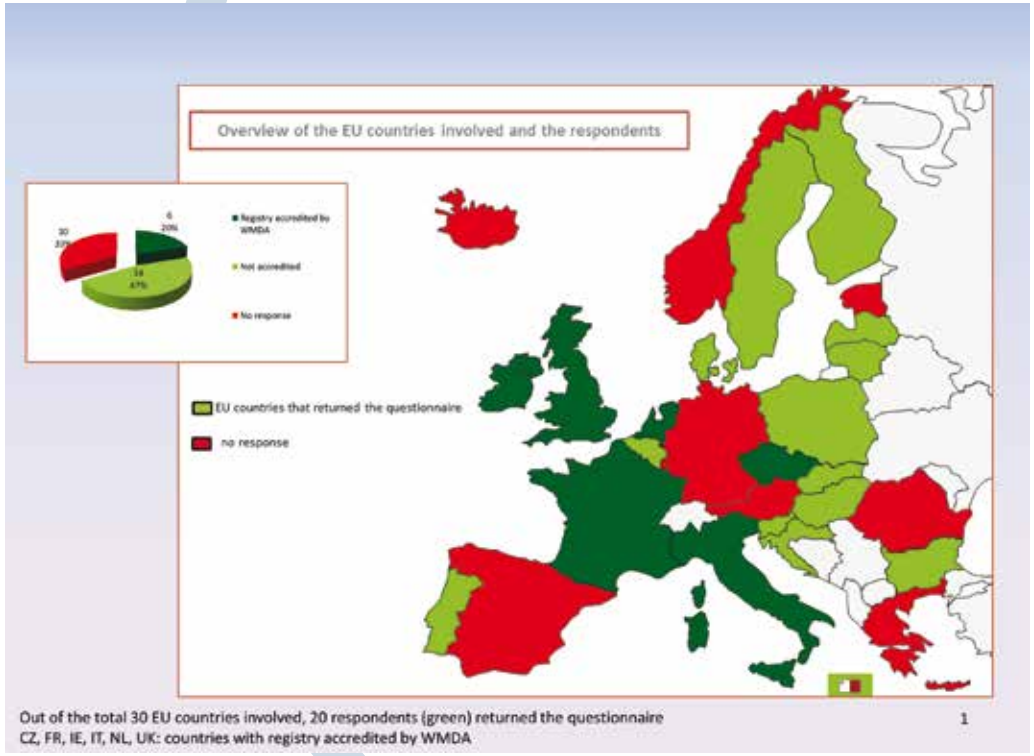
Co- Leaders : the Competent Authority of Croatia - The Ministry of Health and Italy - ISS Centro Nationale di Trapianti

Ministry of Health of the Republic of Croatia (MoH) and the Italian National Institute of Health (ISS) are co-leading this work package, that aims at developing a model for setting up haematopoietic stem cell (HSC) donor follow-up registries at local and national level and a guideline for safety and quality in the field of cord blood banking, compatible with existing worldwide recognised professional standards and European requirements.

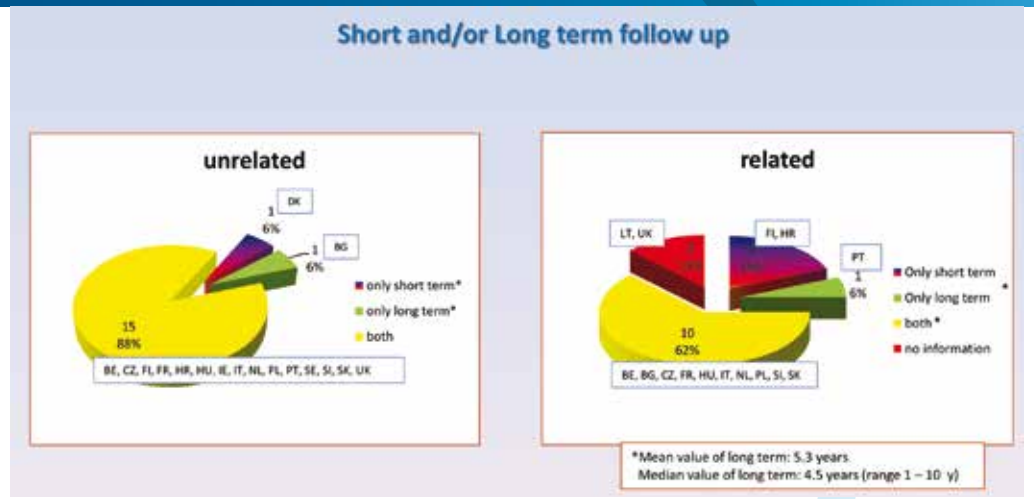
In abutment to the aims three guidance booklets will be delivered during the project: Guidance for Establishing the HSC Donors Follow-up Registry, Guidelines for Cord Blood Banking and Cord Blood Banks Inspection Guidance.

During these first eighteen months of work, the group agreed upon and performed two surveys on the single topics, convening to discuss results and further work during two technical meetings. The meetings took place in Stockholm (Sweden) on Dec 16th 2014 and Rome (Italy) on Sept 23rd 2015.

In collaboration with associated and collaborating partners a questionnaire on HSC donor follow-up was developed and circulated to all in-the-field Competent Authorities. Results on current status on HSC FU registries (related and unrelated donors, practices, data collected) were presented both at Competent authorities meeting in June 2015 as well as during the successive Rome meeting after further validation.
As an example of collected data in the following slides, the details of respondents and percentage of countries performing short and/or long term follow-up for HSC donors are shown:



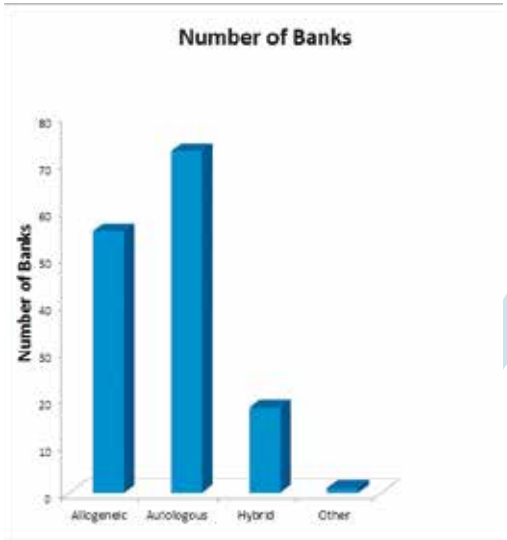
Out of the total 30 EU countries involved, 20 respondents (green) returned the questionnaire
CZ, FR, IE, IT, NL, UK: countries with registry accredited by WMDA

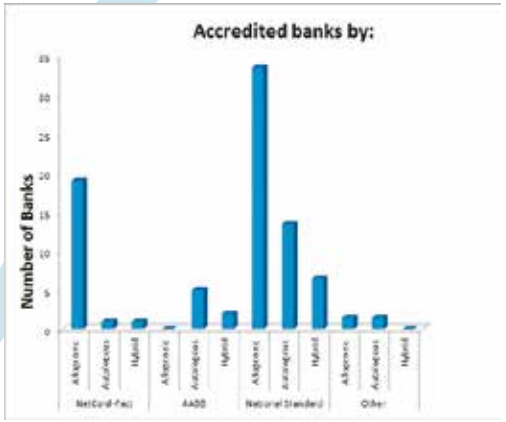


Soon after such analysis, guidance for establishing HSC donors registry is going to be defined during the remaining JA duration.

As far as the Guidelines for Cord Blood Banking are concerned, first task was to identify the status of cord blood banking in Member States and a short questionnaire was circulated to Competent Authorities. The questionnaire was focused on revealing the accreditations and standards in use in the cord blood banking field across the EU and their linkage with legal requirements.

Based on the results of the questionnaire and discussion among partners at first technical meeting fields to be covered are decided and structure of the Guidelines for Cord Blood Banking constructed.
First draft of the Guidelines partners elaborated further during the second technical meeting. Second draft is foreseen to be distributed for comments prior to the Interim meeting.





Cord Blood Banking Inspection Guidance which aims to set harmonised approach for CBB inspections (including inspectors' education and skills, inspection documentation, performance) and mutual recognition of EU inspection bodies in the field. Inspection guidance will be developed on the founds of above named Guidelines.
After the Guidance is completed a practical training for the inspection of CBB will be organised.

Key message of the WP 5
Strengthening safety and quality in HSC donor follow-up process and setting acceptable minimum standards in Cord blood banking will establish common good practice for those fields within Member States.

ARTHIQS EXPECTED OUTCOMES

Regarding Assisted Reproductive Technologies, the main outcome should be the existence in all Member States, at the governmental level, of a sustainable structure: Competent Authorities (or Delegated Bodies, Medical Agencies) with a sufficient knowledge about Assisted Reproductive Technologies issues raised both by the European regulation (European Union Tissues and Cells Directive, cross-border Directive) and by internal national regulation. DG SANTE (Directorate General for Health and Consumers of the European Commission) should benefit from best-informed advice and opinion from each Member States for any consultation or political decision to be taken regarding the field.
The recommendations concerning the set-up of a Haematopoietic Stem Cells donor follow-up registry will set the basic framework for establishing registries as a tool for the upgrade/improvement of safety in Haematopoietic Stem Cells donation.
The guidelines for Cord Blood Banks main outcome will be the establishment of EU common good practices in the field, particularly in those areas where there are notable gaps. Overall outcome will be a significant increase in quality and safety practice in the whole Cord Blood Banks domain, and Competent Authorities having tools to assess the compliance of Cord Blood Banks thanks to emitted guidelines.

ARTHIQS having mainly institutional goals, targeted groups will also be policy makers:
- Member States Ministries of Health and National representative will also have tools to organise Assisted Reproductive Technologies and Haematopoietic Stem Cells national fields, to ensure a well-organised authorisation scheme through inspections, and through trained representatives to defend national positions at the EU level.
Since the guidelines to be generated will be reflecting consensus positions from ARTHIQS partners, the work regarding Assisted Reproductive Technologies and Haematopoietic Stem Cells shall be useful for potential future technical amendments of the current EU legislation for tissues and cells and also in case of a potential revision of this legislation.

ARTHIQS guidance and tools generated will support a direct implementation for the benefit of donors and recipients across the EU, and in a cost-efficient manner for Member States. Importantly, sustainability of ARTHIQS work will be ensured by training for representatives of all 28 Member States in both Assisted Reproductive Technologies

Map of participating countries.

and Haematopoietic Stem Cells, and by a careful dissemination strategy relying on ARTHIQS communication leaders, all partners and collaborators and on professionals and scientific societies.

Associated partners: Agence de la biomédecine (France); State Institute for Drug Control (Czech Republic); Health and Social Care Inspectorate (Sweden); Ministry of Health (Croatia); Centro Nazionale Trapianti – Instituto Superiore di Sanità (Italy); Human Fertilization and Embryology Authority (United Kingdom); Ministry of Health (Malta), Ministry of Health - Department of Mother and Child (Poland); Hellenic Transplant Organisation (Greece); Agence fédérale des médicaments et des produits de santé (Belgium); Bulgarian Executive Agency for Transplantation (Bulgaria); the Paul-Ehrlich-Institut (Germany), Instituto Português de Sangue e da Transplantação (Portugal); Ministry of Health Welfare and Sport (The Netherlands); National Centre for tissue and Cell Banking (Poland); Národná transplantačná organizácia (Slovakia).

Collaborators: The Hungarian National Blood Transfusion Service and the Conselho Nacional de Procriação Medicamente Assistida (Portugal), the World Marrow Donor Association (WMDA) is also represented along with experts from different Member States being JACIE inspectors, participating in experts groups of the European Group for Blood and Marrow Transplantation (EBMT); of FACT, of JACIE; of Netcord- FACT and some being experts from the University Hospital of Liège, Sang i Teixits (Barcelona CBB, Spain) also experts from Vilnius University Hospital (Lithuania); from Ministry of Health (Cyprus); and dedicated experts from Hospital Clinico Universitario Virgen de la Arrixaca in Spain.

The ARTHIQS Consortium would like to highlight that The European Commission, by co-financing projects and Joint Actions under the Health Programme, is greatly contributing to the fields and is promoting a better, safer and wider National and European landscape for Assisted Reproductive Technologies and Haematopoietic Stem Cells for transplantation.

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