



ARHIQS

Assisted **R**eproductive **T**echnologies & **H**aematopoietic stem cells
Improvements for **Q**uality & **S**afety throughout Europe

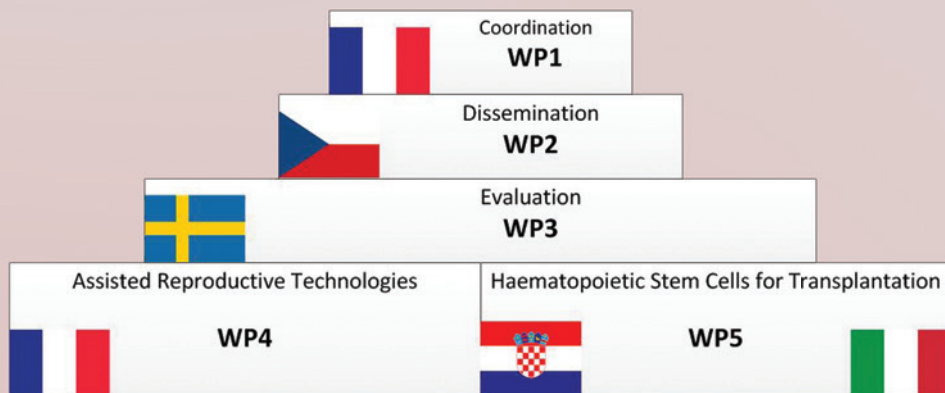
ARHIQS aims to develop guidelines for key aspects of Assisted Reproductive Technologies and Haematopoietic Stem Cells for Transplantations regulations by complementing and developing safety and quality requirements for the benefit of both Donors and Recipients/ ART Beneficiaries.

ARHIQS section on ART is aiming at strengthening and building-up a competence to set an institutional and organisational framework at Competent Authority and delegated bodies levels; hence enhancing gamete donors and ART beneficiaries' safety throughout the EU.

ARHIQS HSC section focuses on increasing donors and recipients' safety by enhancing standards of HSC donation, notably through related and non-related donors' follow-up registry. As a complement, this part of the work also includes drafting of a Guideline for Cord Blood Banking for transplantation entailing the minimum quality and safety requirements for authorising/re-authorising Cord Blood Banks, along with a Vade-Mecum and a Curriculum for inspectors.

ARHIQS 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.

ARTHIQS work and responsibilities are divided in sections designated as work packages (WPs), the horizontal WPs are: Coordination (France: The Agency of Biomedicine, delegated body for Assisted Reproductive Technologies and Haematopoietic Stem Cells), Dissemination (led by Czech Republic; SUKL - Human Tissues and Cells Competent Authority) and Evaluation (led by Sweden: IVO - The Health and Social Care Inspectorate, Competent Authority).



There are two technical WPs: WP4 dealing with Assisted Reproductive Technologies led by France (Agency of Biomedicine) and the WP5 on Haematopoietic Stem Cells for Transplantation led by the Competent Authority of Croatia (The Ministry of Health) and co-led by Italy - ISS National Transplant Centre (public technical and scientific body).

■ WP1: Coordination

Leader : Agency of Biomedicine, France



The Agency of Biomedicine (ABM) operates in four key areas of human biology and medicine: assisted reproductive technologies, prenatal and genetic diagnosis, embryos and stem cell research, and the procurement and transplant of organs – notably thanks to regulation and support offices – tissues and cells.

The coordinator has the overall responsibility of the project coordination and management. Permanently exchanges information on progresses, troubleshooting, deliverables produced and results achieved. 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



SÚKL is a public administration body regulating areas of medicinal products, clinical trials, medical devices, human blood products, human tissues and cells and medicinal cannabis; and is competent to authorise tissue establishments, procurement centres and diagnostic laboratories and to control their activities by regular inspections.

Being in charge of the web site, layman brochure and newsletters, WP2 will ensure that results and deliverables are made available to all relevant stakeholders. WP2 shall list all identified dissemination targets in every Member States and generate a dissemination plan. The dissemination will be completed 4 months after the two technical work packages to ensure dissemination of results.

■ WP3: Evaluation

Leader : Health and Social Care Inspectorate, Sweden



IVO main task is to ensure that the public receives safe, good quality health and social care in accordance with laws and other regulations and is responsible for authorization and permits in these areas.

WP3 will continuously evaluate overall progresses, notably through project meetings attendance, interim reports, feedback from the different evaluation experts and from WP4 and WP5 results and deliverables. Evaluation will notably be performed through surveys and interviews. WP3 will send a brief questionnaire to selected stakeholders to assess if ARTHIQS guidelines were informative, helpful and used. Results from this brief analysis will be presented during final meeting and WP3 report.

■ WP4: Assisted Reproductive Technologies

Leader : Agency of Biomedicine, France



ABM also regulates ART practices, issues recommendations and guidelines for good practices, hosts the ART vigilance system and the national IVF registry, evaluates individual IVF results and activities, follows up of ART beneficiaries, donors and children, reports to the Ministry of Health, informs the public, the parliament and the press.

WP4 aims to provide: i) institutional guidelines to facilitate regulation (quality and safety management; donor/ beneficiaries information, selection, consent; access to fertility preservation etc.), ii) An ART training of one designated representative per Member State and so supporting the setting/ strengthening of a national ART specific organisation, and iii) A Vade-Mecum and a Curriculum for ART Centre inspectors.

■ WP5: Haematopoietic Stem Cells for Transplantation

Leader: Ministry of Health of Croatia

and Co-Leader ISS – National Transplant Centre (CNT), Italy



Ministry of Health (MoH) is the Competent Authority (CA) for blood, tissues and cells, ART and organs. The mission of MoH is the preservation and improvement of health including the protection of public health interests, illness prevention, treatment and rehabilitation of patients.



Centro Nazionale Trapianti

CNT is a public technical and scientific body of the National Health System, under the control of the Italian Ministry of Health, coordinating activities related to organ and tissue donation and transplantation, HSC and ART. CNT also

performs vigilance activities through inspection programme and also detection and management of severe adverse events and reactions.

One of the aims of this WP5 is to develop guidelines for HSC donor follow-up registries to be implemented both locally and nationally. Such guidelines shall target main safety issues; criteria and standard data set; IT specifications; governance for a national registry. Such guidelines will be disseminated to Competent Authorities and HSC donor centres. A guideline for Cord Blood banking (CBB) will be produced in order to harmonise the organisational framework for CB banking at EU level with the aim to increase safety, quality and transparency. These guidelines shall include requirements for authorising CBB and quality and safety standards for CBB. Guidelines will guarantee a higher level of healthcare for both Donors and Recipients.

As a complement, a Vade-Mecum and a Curriculum for CBB inspectors will be developed to provide specificities of the field, which will be followed by a specific training aimed to disseminate the guidelines towards Competent Authorities or representative of delegated body.



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I mprovements for Q uality & S afety throughout Europe

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ARTHIQS consortium is gathering Associated Partners and Collaborators from 18 Member States



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 – Istituto Superiore di Sanità (Italy); Human Fertilization and Embryology Authority (United Kingdom); Instituto Português do Sangue e da Transplantação (Portugal); Ministry of Health (Malta), Department of Mother and Child (Poland); Hellenic Transplant Organisation (Greece); Agence fédérale

Agence de la biomédecine, sources : ARTHIQS 2014, ESRI

des médicaments et des produits de santé (Belgium); Bulgarian Executive Agency for Transplantation (Bulgaria); Ministry of Health, Welfare and Sport (The Netherlands); National Centre for tissue and Cell Banking (Poland); Národná transplantáčná organizácia (Slovakia), The Hungarian National Blood Transfusion Service - OCO 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 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.