

## IPA 2009 Croatia Project Fiche

**HR2009-03-28-11**

### **1. Basic information**

- 1.1 CRIS Number: IPA/2009/21661
- 1.2 Title: Strengthening the Institutional Capacity for Blood, Tissues and Cells
- 1.3 ELARG Statistical Code:
- 1.4 Location: Republic of Croatia

### **Implementing arrangements:**

#### 1.5 Implementing Agency:

Central Finance and Contracting Agency (CFCA)  
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#### 1.6 Beneficiary (including details of SPO):

Ministry of Health and Social Welfare (MHSW)  
Ksaver 200a  
10 000 Zagreb, Republic of Croatia

Croatian Institute of Transfusion Medicine (CITM)  
Blood establishments  
University Hospital Zagreb (Cord Blood bank)  
Tissue establishments  
IVF units

The Senior Programme Officer (SPO) for the project is:

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On a daily basis, the technical counterparts for the project and for reporting to the SPO are:

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**Financing:**

|  |                      |
|--|----------------------|
| 1.7 Overall cost (VAT excluded) <sup>1</sup> : | <b>EUR 2 400 000</b> |
| 1.8 EU contribution (IPA Budget):              | <b>EUR 2 000 000</b> |

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<sup>1</sup> The total cost of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated (see Section 7.6)

1.9 Final date for contracting: 2 years following the date of conclusion of the Financing Agreement

1.10 Final date for execution of contracts: 2 years following the end date for contracting

1.11 Final date for disbursements: 3 years following the end date for contracting

## **2. Overall Objective and Project Purpose**

### 2.1 Overall Objective:

Increasing the availability, quality and safety of blood, tissue and cells for human application in order to assure the highest possible level of public health protection.

### 2.2 Project purpose:

Implementation of the Directive 2002/98/EC on setting standards of quality and safety for the donation, testing, processing, storage and distribution of human blood and Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells in the Republic of Croatia.

### 2.3 Link with AP/NPAA / EP/ SAA

Accession Partnership document (2008/119/EC) with reference to paragraph „Ability to assume the obligations of membership“ within Chapter 28, identifies priorities in the field of Consumer and health protection which requires further alignment with the acquis, including areas of blood, tissues and cells, and to ensure adequate administrative structures and enforcement capacity.

According to Accession Partnership (2008/119/EC) with reference to Chapter 3 Priorities within paragraph “Economic criteria”, Croatia is also expected to continue implementation of comprehensive health care reforms to avoid the accumulation of new payments arrears in the health system and to improve efficiency of health spending (availability of blood, tissue and cells based on self-sufficiency). Also, Chapter 28 Consumer and Health Protection states that special attention should be paid to adequate administrative capacity to upgrade and restructure facilities for handling blood, tissues and cells in order to meet EU technical requirements.

Reference to NPAA. National Programme for the Accession of the Republic of Croatia into the European Union for the year 2008 (NPIEU, May 2008) within Chapter III Ability to assume obligation of membership under Chapter 28 (Consumer and health protection), in the sub chapter B Key Priorities identifies the field of blood and blood composites, cells and tissues as priorities in relation to strengthening of the administrative capacity to be fully compliant with acquis.

In that sense, the main objectives are strengthening administrative capacity for implementation of harmonised laws and related subordinate legislation in the area of blood and

blood components, tissue and cells (accreditation of blood and tissue establishments provision of technical conditions).

#### 2.4 Link with MIPD

Multi-annual Indicative Planning Document (MIPD) 2008-2010 clearly supports areas of intervention that were identified within the Progress Report and Accession Partnership for the Republic of Croatia. In that manner MIPD indicates that the 3<sup>rd</sup> area of intervention will support Croatian authorities by measures aimed at adopting or completing the transposition of the *acquis*.

#### 2.5 Link with National Development Plan

Not applicable.

#### 2.6 Link with national/ sectoral investment plans

Not applicable.

### 3. Description of project

#### 3.1 Background and justification:

MHSW is a Competent Authority for blood, tissue and cells for human application under European Tissue and Cells Directive 2004/23/EC and Blood Directive 2002/98/EC. Therefore MHSW aims to ensure proper implementation of the requirements of the Directives in the Croatian health care system as well as to facilitate the blood and tissue establishments in fulfilling the requirements of set by *acquis*. To achieve this goal MHSW has to be able to perform all Competent Authority tasks in accordance within the requirements of competency stated in the Directives

- setting standards and proper system for licensing and inspection of blood and tissue establishments (including IVF) to ensure that all relevant activities in the field of blood, tissue and cells are compliant with the requirements of quality and safety standards
- designating and implementing a biovigilance (haemovigilance and tissuevigilance) system including all necessary procedures for collection, risk assessment and monitoring of serious adverse events (SAE) and serious adverse reactions (SAR); setting up the system to trace blood, tissues and cells from donor to recipient and vice versa
- supervising and enhancing the national network of tissue banks which can exchange tissue and cells within a national network as well as across Europe, ensuring consistent quality and safety standards
- development of registers (including IVF centres) and statistics data management.

Although the Blood and Tissue Directives are being formally transposed, many of its requirements are not fully implemented yet: quality management systems, traceability and a biovigilance system. One of the main reasons is related to insufficient institutional capacity of the Competent Authority. Additional reasons are related to the lack of funds necessary for the proper and complete reorganisation of transfusion service and implementation of requirements of Directives in the whole blood and tissue system.

The blood reorganisation process started in 2008 and is currently in its first stage (*see Annex III*). The *Plan of Reorganisation of transfusion service* envisage the merge of smaller blood bank centres (decreasing from 21 to 9) creating a new structure of nine (9) blood establishments for collection, processing and testing. Five of these nine blood centres (Regional Institutes for Transfusion medicine) should perform serological testing and two of the nine blood centres should perform nuclear acid testing (NAT)<sup>2</sup>. Transfusion services will operate under a common framework of standards, procedures and with a common information system. One essential element of this programme – the national computing system - has already been funded by the MHSW. This IT system should be operational by the end of 2009 and reorganisation process completed by the end 2010.

CITM is the biggest blood establishment and Referral Centre for Transfusion Medicine of MHSW and since 2001 has achieved and maintains the quality standards according to ISO 9001/2000 issued by Lloyd/UK. CITM provide almost 50% of the total amount of the national needs for blood components for clinical use (*see Annex III*). Therefore CITM is selected to be a pilot project within the IPA TAIB National Programme for 2009 that aims toward improving the quality and safety of plasma for clinical use through increasing percentages of fresh frozen plasma (FFP) production and an implementation of plasma inactivation method.

With funds from this project, substantial improvements will be reached in the level of CITM performance. With the necessary equipment, quality management systems and blood processing methods (plasma inactivation method), CITM will become the centre of excellence, a training centre and a reference model for all other blood establishments.

Transplantation and tissue banking activities started in Croatia in the 1980s, but the first data on banking and transplantation activities on a national level were collected in 2007 and 2008. Those data were sent to the EURO CET registry (*see Annex III*). At present there are three bone banks, one eye bank, one multi-tissue bank (skin and bone), one cord blood bank and three autologous haematopoietic stem cells banks, processing approximately 300-400 bone grafts, 70-80 cornea grafts, 500 units of cord blood, and 10 000 cm<sup>2</sup> of skin per year. The actual projected needs of tissue and cells for clinical use are estimated to be higher than the tissues and cells currently available.

However most of the tissue establishments (TEs) at this stage do not have adequate facilities and quality management systems to fulfil relevant EC Directives' requirements in accordance with all regulations. There is government supported funding for the tissue and cells through the basic health care insurance, which however is limited.

University Hospital Centre Zagreb is the most experienced hospital in tissue banking in Croatia (bones, autologous HSC, eye and cord blood), but historically different tissues are stored in different departments. Such a model is costly and in demand for current and modern quality standards. Therefore, University Hospital Zagreb is underway to centralise all banking

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<sup>2</sup> See Annex III for description of Institutional Framework of Blood Transfusion

activities into one multi-tissue bank. The process of centralisation started in 2009 by incorporating the bone bank from the Department of Orthopaedic Surgery in Cord Blood Bank (CBB) which is unit of Department of Transfusion Medicine and Cell Therapy. Hospital development plans anticipate establishing one multi-tissue bank, fulfilling all technical requirements, within the next 3-5 years.

According to EC Assessment Mission Final Report (INT MARKT EXP 30275), CBB is close to fulfilling the requirements of the acquis. To achieve full compliance and to facilitate the hospital development plan, which anticipates upgrade of CBB into a multi-tissue bank, additional investment in this facility is needed and justified; increasing storage capacity and establishing a laboratory for quality control as a reference laboratory for all other HSC collection sites in the country (University Hospital Centre Zagreb, Department of Internal Medicine is appointed as Reference Centre for Stem Cell Treatment of MHSW in 2008). Therefore CBB is included within this project under the IPA TAIB National Programme for 2009.

The Project will help Croatia to improve quality systems in CBB, increasing safety and quality of HSC cells for therapeutic use and supporting CBB to become the bank of excellence and reference training centre. Substantial improvements will be reached with funds from this project on the level of equipment, quality systems and storage capacity.

### 3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)

The project will upgrade the working practices of the Competent Authority by strengthening institutional and administrative capacity of the Authority. The transfer of the European institutional models and expertise will bring about a catalytic effect. The effect will be seen in the operations of the Competent Authority for blood, tissues and cells by establishing a new system for licensing, inspection and supervision of blood and tissue establishments, according to the European regulations, and at the same time providing support to the activities of blood and tissue establishments.

Positive impact will be evident, in the area of the safety and quality standards of blood and blood products. Residual risk of transfusion transmitted HIV (1,8), HBV (1,6) and HCV (3,6) infection in Croatian blood recipients was calculated on donations collected in CITM (50% of all donations were collected in Croatia). Therefore inactivation of pathogens would be a good measure for additionally reducing the risk of transmission blood borne viruses (*see Annex III*).

Training courses and seminars for various groups of health professionals involved in blood and blood components practice will increase their knowledge and qualifications in the fields of production of blood components and transfusion therapy.

This project will have a positive impact on the safety and quality of tissues and cells for human application through strengthening of institutional capacity and providing financial support for supplying facilities with state-of-the-art medical equipment by supporting the development of two centres of excellence, one for blood, and one for tissue (see Project Purpose). These centres will become the reference training centres, setting and updating national standards and disseminating the knowledge and methodology to other blood and tissue establishments.

The institutional sustainability will be ensured in two ways: by documentary tools provided within the Institution Building Component (guidelines, reports, training materials etc) and also by the staff of the Competent Authority supporting blood and tissue establishments in achieving common and cooperative working standards.

The financial sustainability will be ensured by planning adequate means for the maintenance of the procured equipment.

In terms of cross-border impact this project will guarantee the same standards of quality and safety of blood, tissue and cells exchanged with other EU member states.

### 3.3 Results and measurable indicators:

#### *Competent Authority (CA)*

In the field of CA emphasis should be given on institutional capacity building of Ministry of Health and Social Welfare (MHSW) as the Competent Authority for blood, tissues and cells. Accordingly, special importance will be put on harmonising national activities with European directives and relevant professional institutions in the field of blood, tissue and cell banking. Therefore, results for CA are as follows:

- Competent Authority for blood, tissue and cells strengthened and fully operating, with sufficient expertise and administrative capacities

*Indicator:* CA provided with all documentary tools on the competencies in the field of blood, tissue and cells (guidelines, training programs SOPs, training material...). CA staff fully trained and provided with expertise in the fields of their competencies.

- Training programs as well as training curricula and materials developed for inspectors involved in licensing and inspecting of blood, tissues and cell establishments.

*Indicator:* Inspectors properly trained and certificated for licensing and inspecting procedure.

- Improved process for licensing and inspections of blood and tissue establishments to ensure that inspections and control measures are carried out in efficient way and at consistent level.

*Indicator:* National guidelines for licensing and inspection of Blood and Tissue Establishments designed and distributed to all blood and tissue establishments (guidelines for licence and inspection, initial application forms, document checklist, inspection check list, format for inspection and inspectors report...).

- Designated biovigilance system structure implemented at the national level

*Indicator:* Guidelines and Standard operating procedures on biovigilance system, designed and distributed to all blood and tissue establishments. CA staff and health professionals in blood and tissue establishments properly trained and certificated

- National reporting systems in place for all issues of blood, tissue and cells which will allow sharing of information with other member states.

*Indicator:* Communication protocols (including Rapid alert protocol) developed and distributed to all blood and tissue establishment. Yearly and other relevant reports on SAR and SAE collected. Register designed and publicly available. Responsible persons trained in a daily statistics management.

- Supervising and enhancing the national network of tissue banks which can exchange tissue and cells within a national network as well as across Europe, ensuring consistent quality and safety standards

*Indicator:* designed procedures and protocols for import and export of tissue and cells ensuring the same quality standards. CA staff properly trained.

- Defining preconditions for implementation of common coding system and traceability requirements

*Indicator:* Consultation and guidance in database designing, Expert report

### *Tissue and cells*

The aim in tissue and cells part of the project is to build a national system for setting and updating national standards on quality and safety of donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells according to Directive 2004/23/EC. Standards that should be respected are: standards of the European Association of Tissue Bank (EATB), international standards for cord blood collection, processing, testing, banking, selection and release issued by NetCord and Foundation for Accreditation for Cell Therapy (FACT) and standards for blood and marrow progenitor cell processing, collection and transplantation from the Joint Accreditation Committee of ISCT Europe and EBMT (JACIE). It is foreseen to upgrade one tissue establishment as the centre of excellence for tissue and cell banking at the national level, which will become the training centre for other tissue establishments. The results are:

- Development of national standards for good tissue/cells practice according to Directive 2004/23/EC,

*Indicator:* Good tissue practise defined and published as standard for all tissue establishments.

- Administrative procedure related to application for licencing and inspection procedure (guidelines for inspection, initial application forms and documents checklist, inspection checklist, quality system) developed and distributed

*Indicator:* Guidelines for Inspection of Tissue Establishments (guidelines for licencing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report) published.

- Designated and distributed model of materials for development of documentation needed for implementation of quality management system in tissue banks, including Manual for Implementation of Quality Management System in Tissue Establishments, which cover all basic elements of a quality system related to good tissue practise.

*Indicator:* Published Manual for Implementation of Quality Management System in Tissue Establishment

- CBB upgraded of laboratory (cell) for quality control methods and technical conditions for storing various types of tissues and cells.

*Indicator:* new quality control methods implemented in CBB; new equipment installed and staff trained in handling it.

- CBB upgraded as centre of excellence for good tissue practise.

*Indicator:* Licence for multi- tissue bank activities issued by CA. Good tissue practise implemented in CBB, CBB staff trained in transfer of “know – how”, sustainable and structured training programs organized, and training of trainers conducted.

- National training program as well as training curricula and materials for various groups of health professionals and all institutions throughout the country involved in donation, procurement, testing, processing, preservation, storage and distribution of tissue and cells designed.

*Indicator:* Training on good tissue practise for health professionals involved in donation, procurement, testing, processing, preservation, storage and distribution of tissue and cells, started.

### *Blood*

Results related to human blood will comprise building a national system for setting and updating national standards on quality and safety of donation, testing, processing, storage and distribution of human blood, according to Directive 2002/98/EC. These will be supported by reorganisation process of national transfusion system, thus optimising the use of blood and blood products. To facilitate that, CITM will be upgraded as the centre of excellence for blood collection, processing and testing at a national level, which will become the training centre for other blood establishments. Results for human blood component are:

- Development of National standards on quality and safety of human blood according to blood Directive 2002/98/EC and Guide to the preparation, use and quality assurance on blood components issued by EDQM.

*Indicator:* National standards on quality and safety of human blood implemented in CITM as reference (standard) model for all Blood Establishments.

- Administrative procedures related to licencing and inspection (guidelines for licencing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report) designated and distributed

*Indicator:* Published Guidelines for Inspection of Blood Establishment (guidelines for licencing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report). CITM staff trained.

- Designated and distributed model of materials for development of documentation needed for implementation of quality management system in Blood establishments

*Indicator:* Manual for Implementation of Quality Management System in Blood Establishments which covers the all basic element of quality systems and maintenance of standard operating procedure, available and published.

- CITM upgraded of as centre of excellence for sharing of best operating practises according to the national blood standards and quality management system developed under the above point.

*Indicator:* Licence for CITM issued by CA. CITM staff trained in transfer of “know – how”, sustainable and structured training programs organized, and training of trainers conducted.

- CITM upgraded of as a reference model for other regional centres in the field of plasma inactivation method.

*Indicator:* CITM equipped with state-of-the-art medical equipment. CITM staff trained for plasma inactivation and for transfer of “know – how”. Training program for regional centres organized and conducted

- National training program as well as training curricula and materials for various groups of health professionals and all institutions throughout the country involved in donation, procurement, testing, processing, preservation, storage and distribution of blood designed.

*Indicator:* First Training for health professionals in blood establishments and blood users started.

- CITM in function as operational reporting (haemovigilance) system at the national level

*Indicator:* National haemovigilance guidelines prepared and distributed to other blood establishments. Database provided. Education started.

### 3.4 Activities:

Experts’ help will be needed for development of the licensing and inspection procedures, development of the licensing inspection plan and guidelines, support in the development of the Department's operational program, and procedures for surveillance of tissue banks. Furthermore, support will be needed for drafting forms such as the Final Inspection Report and other operational reports and documents.

### Component I - Twinning

Twining has to be focused on:

- Analysis of all blood establishments including workspaces, human resources and equipment. Report should be composed of recommendations for improvement, specific to each facility. Consultations, advice, assistance and expertise in implementing Directive 2002/98/EC and Guide to the preparation, use and quality assurance of blood components

- Review and, if necessary, revise or draft the national policy for blood, tissue and cells banking
- Transfer of EU member states best institutional practices and developing potential for their implementation in the work of Croatian Competent Authority
- Planning and implementing licensing and inspection systems for authorisation and surveillance of blood, tissue and cell establishments according to Directive 2004/23/EC and Directive 2002/98/EC
- Consultations, advice, assistance and expertise in designing and implementing all aspects of biovigilance system for blood, cells and tissues according to Directive EC No 2006/86/EC in regards to traceability requirements, notification of serious adverse events and serious adverse reactions
- Leading the Expert committee for development of quality management systems and preparing Manual for Implementation of Quality Management System. Expert committee will be nominated by MHSW and will consist of representatives from all relevant professions. Manual for Implementation of Quality Management System has to cover all aspects of quality in tissue and cell establishments. It will consist of two parts: general requirements for quality management systems and specific sections which will cover unified good tissue practise (for example: donor screening and selection, tissue procurement, processing and storage, donor testing, est.), training manuals and forms including donor records and follow up forms. After the testing phase in one multi-tissue bank these documents will be disseminated to all tissue establishments in Croatia.
- Leading the Expert committee for development of quality management systems and preparing Manual for Implementation of Quality Management System in blood establishments in Croatia.
- Preparation of workshops on legal provisions, licensing process and inspection surveillance for blood and TE sector.
- Training of staff of Competent Authority and members of Expert Committee to have an additional capacity on the national and international level to manage forthcoming issues related to quality and safety of blood, tissue and cells
- Training courses for various groups of health professionals involved in blood and tissue banking activities:
  - medical doctors responsible for donor screening, selection and production
  - medical directors of blood, tissue and cell establishments
  - technical staff
  - medical doctor users of blood components and tissue grafts
- Consultations for tissue bank professionals to implement Good Tissue Practice (GTP) in each aspect of tissue and cell banking activities including designing the tissue bank facilities according to the specific Directive 2004/23/EC requirements.

## Component II – Purchase of equipment for upgrading of two centres of excellence

Investment will be focused on (see *Annex V*):

- Procurement and delivery of laboratory equipment for one blood establishment (CITM) for :
  1. improving immunohaematology testing of blood donors
  2. increasing quality and safety of FFP
- Procurement and delivery of laboratory equipment for one tissue establishment (CBB) for :
  1. upgrading of quality control laboratory
  2. increasing storage capacity for different types of tissues and cells

### 3.5 Conditionality and sequencing:

Regulatory framework for blood, tissue and cells, which has already been completed in accordance to EU Directives requirements. Roles and responsibilities of the Competent Authority for blood, tissue and cells are additionally set up through Ordinance on Amendments on Internal Structure of MHSW, adopted on 29 December 2008, and Act Amending Act on Explanation and Transplantation of Human Body Parts in Therapeutic Purpose OG 45/09. With regard to administrative capacity, the issue has been extensively discussed with EC representatives\* and Croatian side has provided to EC a skeleton structure of the foreseen document on administrative capacity in the field of blood, tissue and cells (*Annex III*).

The Project would be carried out through twinning contract and supply contracts, starting with an institution building component first, followed by a supply contract. The project implementation will include several steps:

1. estimation of expert selection and twinning contract
2. strengthening of Competent Authority for blood, tissue and cells in the field of inspection, licensing and biovigilance system
3. review of the national policies for blood, tissue and cells
4. creation of national standards and guidelines on good tissue practice and quality system
5. tender and supply contract
6. implementation of quality management system in pilot centre and installation of equipment
7. training programs for various groups of professionals involved in blood, tissue and cell banking to increase their qualifications

### 3.6 Linked activities

Following the employment of new employees within the Department for Inspection and Monitoring of Blood, Tissues and Cells, the attendance of new employees and health inspectors to professional training and seminars has been planned with regards to the auditing and inspections of tissue and cell establishments and implementing of other tasks within their stipulated competence.

Education will be carried out by using the TAIEX technical assistance within the framework of EC funded education programmes for tissues and cells.

Under TAIEX 2009 Croatian Competent Authority representatives and health professionals in the field of tissue and cells will participate in the following events:

- workshop on Tissue banking management for regulators, with the purpose to adopt competencies in the tissue banking practices; quality management system; biovigilance, and risk assessment inspection methodology (**ref. 10055**)
- workshop on procurement and processing of tissue and cells as regards to tissue and cells donor selection and screening, different type of tissue/cell procurement (theoretical and practical skills), tissue processing, quality control (**ref. 10057**)
- Expert mission on national plan for tissue and cell establishments to manage development of, and optimise the investment in the tissues and cells field, in order to meet national needs in an efficient manner (**ref. 10058**)
- Expert mission on improvement of safety and quality of tissue and cells. The tissue establishments as organized today do not fulfil safety and quality requirements according to EUCTD. An upgrade is needed in all tissue banks, including improvement of working methodology in clean room laboratory and adapting the infrastructure of the premises according to EUCTD's requirements (**ref. 10054**)
- Study visit to tissue bank and competent authority. This visit is planned for Competent Authority experts to better understand and implement necessary requirements for the organisation of the TC inspections in accordance with EC legislation (**ref. 10059**) (planned for June 2009)
- Study visit to review quality management system in tissue banks. Area of interest is implementation of QMS in tissue banks (including ISO certification), skin and bone processing, tissue engineering, advanced therapy (**ref. 10060**)

Further education and expertise are planned to be provided through the twinning component of this project, strengthening the institutional capacity for blood, tissues and cell.

The TAIEX activities will not interfere with this project but will secure education of our experts to ease its implementation.

Croatia also uses the EU co-funded project EUSTITE dealing with training of inspectors and developing a traceability vigilance model for tissues and cells. So far two Croatian representatives have been trained and licensed by the EUSTITE project and another representative will be attending the next EUSTITE training course in Italy.

Other training possibilities of personnel abroad are encouraged and supported through TAIEX assistance and through ESHRE EBCOG (European Board and College of Obstetrics and Gynaecology) certification and workshops for embryologists that can be found in several EU member states.

With regard to the national registry, Croatia is taking part in the EURO CET Project (with the possibility of being introduced to the Belgian Register of Assisted Procreation (BELRAP), which is under consideration as well).

### 3.7 Lessons learned

Building on the experience gained from the Assessment Mission of Services Related to Blood, Tissues and Cells in Croatia held on 02-06 June 2008, the MHSW has learned that although the existence of the expert capacity and long time practice in the field of blood, tissue

and cells, the Republic Croatia has not yet to date ensured full implementation of EU standards.

Therefore, effective establishment and strengthening of the institutional capacity is needed as well as upgrading the blood transfusion centre and TE.

Since the European Assisted Conception Consortium (EACC) is a body assisting EU member states in interpreting and implementing the EUCTD, Croatia will apply for membership to ESHRE's (EACC) in order to communicate and exchange experience with EU member states.

#### 4. Indicative Budget (amounts in EUR)

|  |        |         | SOURCES OF FUNDING |                     |                            |             |                              |             |                 |                        |              |                      |       |
|--|--------|---------|--------------------|---------------------|----------------------------|-------------|------------------------------|-------------|-----------------|------------------------|--------------|----------------------|-------|
|  |        |         | TOTAL EXP.RE       | TOTAL PUBLIC EXP.RE | IPA COMMUNITY CONTRIBUTION |             | NATIONAL PUBLIC CONTRIBUTION |             |                 |                        |              | PRIVATE CONTRIBUTION |       |
| ACTIVITIES                                       | IB (1) | INV (1) | EUR (a)=(b)+(e)    | EUR (b)=(c)+(d)     | EUR (c)                    | % (2)       | Total EUR (d)=(x)+(y)+(z)    | % (2)       | Central EUR (x) | Regional/Local EUR (y) | IFIs EUR (z) | EUR (e)              | % (3) |
| Activity 1. Establishment of Competent Authority |        |         |                    |                     |                            |             |                              |             |                 |                        |              |                      |       |
| Twining contract                                 | X      | –       | 1 000 000          | 950 000             | 950 000                    | 95          | 50 000                       | 5           | 50 000          |                        |              |                      | –     |
| Activity 2 Supply of medical equipment           |        |         |                    |                     |                            |             |                              |             |                 |                        |              |                      |       |
| Supply contract 2.                               | –      | X       | 1 400 000          | 1 050 000           | 1 050 000                  | 75          | 350 000                      | 25          | 35 000          |                        |              |                      | –     |
| TOTAL IB   |        |         | 1000 000           | 950 000             | 950 000                    | 95          | 50 000                       | 5           | 50 000          |                        |              |                      |       |
| TOTAL INV  |        |         | 1 400 000          | 1 050 000           | 1 050 000                  | 75          | 350 000                      | 25          | 350 000         |                        |              |                      |       |
| <b>TOTAL PROJECT</b>                             |        |         | <b>2 400 000</b>   | <b>2 000 000</b>    | <b>2 000 000</b>           | <b>83,3</b> | <b>400 000</b>               | <b>16,7</b> | <b>400 000</b>  |                        |              |                      |       |

NOTE: DO NOT MIX IB AND INV IN THE SAME ACTIVITY ROW. USE SEPARATE ROW

Amounts net of VAT

(1) In the Activity row use "X" to identify whether IB or INV

(2) Expressed in % of the **Public** Expenditure (column (b))

(3) Expressed in % of the **Total** Expenditure (column (a))

## 5. Indicative Implementation Schedule (periods broken down per quarter)

| Contracts         | Start of Tendering | Signature of contract | Project Completion |
|-------------------|--------------------|-----------------------|--------------------|
| Twinning Contract | 2Q 2010            | 4Q 2010               | 4Q 2011            |
| Supply Contract   | 3Q 2010            | 4Q 2010               | 2Q 2011            |

All projects should in principle be ready for tendering in the 1<sup>st</sup> Quarter following the signature of the FA

## 6. Crosscutting issues (equal opportunity, environment, etc...)

### 6.1 Equal Opportunity

Based on the fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed because of equal access regardless of gender, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

### 6.2 Environment

Not applicable.

### 6.3 Minorities

Based on the fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed on the basis of equal opportunity for minorities.

## ANNEXES

- I- Log frame in Standard Format
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(\*) non standard aspects (in case of derogation to PRAG) also to be specified

**ANNEX I: Logical framework matrix in standard format**

|   |  |   |  |
|---|--|---|--|
| <b>STRENGTHENING THE INSTITUTIONAL CAPACITY FOR BLOOD, TISSUES AND CELLS</b>  |  | Programme name and number<br><b>IPA 2009</b>  | [Cris number]  |
| Ministry of Health and Social Welfare (MHSW),<br><br>Croatian Institute of Transfusion Medicine (CITM),<br><br>Blood establishments,<br><br>University Hospital Zagreb,<br><br>Tissue and cells establishments,<br><br>IVF units.                                       |  | Contracting period expires:<br><br>Two years following the date of conclusion of the Financing Agreement (FA)   | Disbursement period expires:<br><br>Three years following the end date for contracting                               |
|   |  | <b>Total budget: EUR 2 400 000</b>  | <b>IPA budget: EUR 2 000 000</b>   |
| <b>Overall objective</b>  | <b>Objectively Verifiable Indicators</b>   | <b>Sources of Verification</b>  |  |
| Increasing the availability, quality and safety of blood, tissue and cells for human application in order to assure the highest possible level of public health protection.   | Capability of institutions involved to work under the requirements of Directives 2002/98/EC and 2004/23/EC achieved.   | <ul style="list-style-type: none"> <li>• National register on licensed blood , tissue and cells establishments</li> <li>• Annual report on tissue, cells and blood activities for Republic of Croatia</li> <li>• National biovigilance report sent to EC</li> </ul> |  |
| <b>Project purpose</b>  | <b>Objectively Verifiable Indicators</b>   | <b>Sources of Verification</b>  | <b>Assumptions</b>   |
| Implementation of the Directive 2002/98/EC on setting standards of quality and safety for the donation, testing, processing, storage and distribution of human blood and Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, | <ol style="list-style-type: none"> <li>1. Competent Authority operating in accordance to EU Directives requirements</li> <li>2. One tissue bank fully implemented Directive 2004/23/EC requirements and</li> </ol> | <ol style="list-style-type: none"> <li>1. a. Licenses granted to blood and tissue establishments issued by a competent authority.</li> <li>1. b. Guidelines and annual reports for biovigilance published .</li> </ol>  | <p>MHSW commitment and support</p> <p>Necessary political support</p> <p>Funding mechanism for tissues and cells</p> |

|   |  |   |  |
|---|--|---|--|
| <p>testing, processing, preservation, storage and distribution of human tissues and cells in the Republic of Croatia.</p>   | <p>granted licence for multi-tissue banking by the competent authority.</p> <p>3.CITM upgraded of as a reference model for other regional centres in the field</p>   | <p>1.c. Registries and Annual reports of blood and tissue and cells activities published</p> <p>1. d. Training certificates.</p> <p>2.Inspection report</p> <p>3.Training program for regional centres organized and conducted</p>  | <p>as well as blood transfusion establishments in place</p>  |
| <p><b>Results</b></p>   | <p><b>Objectively Verifiable Indicators</b></p>  | <p><b>Sources of Verification</b></p>   | <p><b>Assumptions</b></p>  |
| <p>A - COMPETENT AUTHORITY</p> <p>1) Competent Authority for blood, tissue and cells strengthened and fully operating, with sufficient expertise and administrative capacities</p> <p>2) Training programs as well as training curricula and materials developed for inspectors involved in licensing and inspecting of blood, tissues and cell establishments.</p> <p>3) Improved process for licensing and inspections of blood and tissue establishments to ensure that inspections and control measures are carried out in efficient way and at consistent level.</p> | <p>A - COMPETENT AUTHORITY</p> <p>1. CA provided with all documentary tools on the competencies in the field of blood, tissue and cells (guidelines, training programs SOPs, training material...). CA staff fully trained and provided with expertise in the fields of their competencies.</p> <p>2. Inspectors properly trained and certificated for licensing and inspecting procedure.</p> <p>3. National guidelines for licensing and inspection of Blood and Tissue Establishments designed and distributed to all blood and tissue establishments (guidelines for licensing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report)</p> | <ul style="list-style-type: none"> <li>• Training Certificates</li> <li>• National System reports</li> <li>• Project reports</li> <li>• Inspection reports by recognized body to include assessment of quality and haemovigilance systems in place, staff proficiency, documentation systems, etc.</li> <li>• Regular annual national reporting of blood establishments.</li> <li>• Staffing records and documentation available</li> </ul> | <ul style="list-style-type: none"> <li>• Government commitment and support</li> <li>• Good coordination and real-time information transfer from all blood establishment and blood users</li> <li>• Adequate funding for the project</li> </ul> |

|   |   |  |  |
|---|---|--|--|
| <p>4) Designated biovigilance system implemented at the national level</p> <p>5) National reporting system in place for all issues of blood, tissue and cells which allows sharing of information with other member states.</p> <p>6) Supervising and enhancing the national network of tissue banks which can exchange tissue and cells within a national network as well as across Europe, ensuring consistent quality and safety standards</p> <p>7) defining preconditions for implementation of common coding system and traceability requirements</p> | <p>4. Guidelines and Standard operating procedures on biovigilance system designed and distributed to all blood and tissue establishments. CA staff and health professionals in blood and tissue establishments properly trained and certificated</p> <p>5. Communication protocols (including Rapid alert protocol) developed and distributed to all blood and tissue establishment. Yearly and other relevant reports on SAR and SAE collected. Register designed and publicly available. Responsible persons trained in a daily statistics management.</p> <p>6. Designed procedures and protocols for import and export of tissue and cells ensuring the same quality standards. CA staff properly trained.</p> <p>7. Consultation and guidance in database designing, Expert report.</p> |  |  |
| <p>B - TISSUE AND CELLS</p> <p>1) Development of national standards for good tissue/cells practice according to Directive 2004/23/EC.</p>   | <p>B - TISSUE AND CELLS</p> <p>1. Good tissue practise defined and published as standard for all tissue establishments.</p>   |  |  |

|  |   |  |
|--|---|--|
| <p>2) Administrative procedure related to application for licencing and inspection procedure (guidelines for licensing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report) developed and distributed</p> <p>3) Designated and distributed model of materials for development of documentation needed for implementation of quality management system in tissue banks, including Manual for Implementation of Quality Management System in Tissue Establishments which cover all basic elements of a quality system related to good tissue practise.</p> <p>4) CBB advanced with new quality control methods and technical conditions for storing various types of tissues and cells.</p> <p>5) CBB upgraded as centre of excellence for good tissue practise.</p> <p>6) National training program as well as training curricula and materials for various groups of health professionals and all institutions throughout the country involved in donation, procurement, testing, processing,</p> | <p>2. Guidelines for licencing of Tissue Establishments (guidelines for licensing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report) published</p> <p>3. Published Manual for Implementation of Quality Management System in Tissue Establishment</p> <p>4. New quality control methods implemented in CBB; new equipment installed and staff trained in handling it.</p> <p>5. Licence for multi- tissue bank activities issued by CA. Good tissue practice implemented in CBB, CBB staff trained in transfer of “know – how”, sustainable and structured training programs organized, and training of trainers conducted.</p> <p>6. Training on good tissue practise for health professionals involved in donation, procurement, testing, processing, preservation, storage and distribution of tissue and cells, started.</p> |  |
|--|---|--|

preservation, storage and distribution of tissue and cells, designed.

C – BLOOD

1) Development of National standards on quality and safety of human blood according to blood Directive 2002/98/EC and Guide to the preparation, use and quality assurance on blood components issued by EDQM.

2) Administrative procedures related to licencing and inspection (guidelines for licensing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report.), designated and distributed

3) Designated and distributed model of materials for development of documentation needed for implementation of quality management system in Blood establishments

4) CITM upgraded of as centre of excellence for sharing of best operating practises according to the national blood standards and quality management system developed under the above point.

5) CITM upgraded of as a reference model for other regional centres in the

C – BLOOD

1. National standards on quality and safety of human blood implemented in CITM as reference (standard) model for all Blood Establishments.

2. Published Guidelines for Inspection of Blood Establishment (guidelines for licensing and inspection, initial application forms, document checklist, inspection checklist, format for inspection and inspectors report). CITM staff trained.

3. Manual for Implementation of Quality Management System in Blood Establishments which covers the all basic element of quality systems and maintenance of standard operating procedure, available and published.

4. Licence for CITM issued by CA. CITM staff trained in transfer of “know – how”, sustainable and structured training programs organized, and training of trainers conducted.

5. CITM equipped with state-of-the-art medical equipment. CITM staff

| <p>field of plasma inactivation method.</p> <p>6) National training program as well as training curricula and materials for various groups of health professionals and all institutions throughout the country involved in donation, procurement, testing, processing, preservation, storage and distribution of blood designed.</p> <p>7) CITM in function as operational reporting (haemovigilance) system at the national level.</p>  | <p>trained for plasma inactivation and for transfer of “know – how”. Training program for regional centres organized and conducted.</p> <p>6. First Training for health professionals in blood establishments and blood users started.</p> <p>7. National haemovigilance guidelines prepared and distributed to other blood establishments. Database provided. Education started.</p> |                               |  |
|--|---|-------------------------------|--|
| <b>Activities</b>  | <b>Means</b>  | <b>Specification of costs</b> | <b>Assumptions</b>   |
| <p><b>Component I - Twinning</b></p> <p>Analysis of all blood establishments including workspaces, human resources and equipment. Report should be composed of recommendations for improvement, specific to each facility. Consultations, advice, assistance and expertise in implementing Directive 2002/98/EC and Guide to the preparation, use and quality assurance of blood components</p> <p>Review and, if necessary, revise or draft the national policy for blood, tissue and cells banking</p> | <p>1. Twinning Covenant</p>   | <p>Twinning - 1 MEUR</p>      | <p>Good co-operation with Twinning team</p> <p>Allocated and committed staff</p> |

|   |  |  |  |
|---|--|--|--|
| <p>Transfer of EU member states best institutional practices and developing potential for their implementation in the work of Croatian Competent Authority</p> <p>Planning and implementing licensing and inspection systems for authorisation and surveillance of blood, tissue and cell establishments according to Directive 2004/23/EC and Directive 2002/98/EC</p> <p>Consultations, advice, assistance and expertise in designing and implementing all aspects of biovigilance system for blood, cells and tissues according to Directive EC No 2006/86/EC in regards to traceability requirements, notification of serious adverse events and serious adverse reactions</p> <p>Leading the Expert committee for development of quality management systems and preparing Manual for Implementation of Quality Management System.</p> <p>Leading the Expert committee for development of quality management systems and preparing Manual for Implementation of Quality Management System in blood establishments in Croatia.</p> <p>Preparation of workshops on legal provisions, licensing process and inspection surveillance for blood and TE sector.</p> |  |  |  |
|---|--|--|--|

|   |                           |                          |  |
|---|---------------------------|--------------------------|--|
| <p>Training of staff of Competent Authority and members of Expert Committee to have an additional capacity on the national and international level to manage forthcoming issues related to quality and safety of blood, tissue and cells.</p> <p>Training courses for various groups of health professionals involved in blood and tissue banking activities.</p> <p>Consultations for tissue bank professionals to implement Good Tissue Practice (GTP) in each aspect of tissue and cell banking activities including designing the tissue bank facilities according to the specific Directive 2004/23/EC requirements.</p> <p><b>Component II – Purchase of equipment for upgrading of two centres of excellence</b></p> | <p>2. Supply contract</p> | <p>Supply - 1,4 MEUR</p> | <p>Successful purchase and installation of equipment</p>   |
|   |                           |                          | <p><b>Preconditions</b></p> <p>Regulatory framework for blood, tissue and cells, in accordance to EU Directives requirements, adopted.</p> |

**ANNEX II: amounts (in EUR) Contracted and disbursed by quarter for the project**

| <b>Contracted</b> | <b>4Q2009</b> | <b>1Q2010</b> | <b>2Q2010</b> | <b>3Q2010</b> | <b>4Q2010</b>    | <b>1Q2011</b>    | <b>2Q2011</b>    | <b>3Q2011</b>    | <b>4Q2011</b>    |
|-------------------|---------------|---------------|---------------|---------------|------------------|------------------|------------------|------------------|------------------|
| Contract 1        |               |               |               |               | 1 000 000        |                  |                  |                  |                  |
| Contract 2        |               |               |               |               | 1 400 000        |                  |                  |                  |                  |
| <b>Cumulated</b>  |               |               |               |               | <b>2 400 000</b> |                  |                  |                  |                  |
| <b>Disbursed</b>  | <b>4Q2009</b> | <b>1Q2010</b> | <b>2Q2010</b> | <b>3Q2010</b> | <b>4Q2010</b>    | <b>1Q2011</b>    | <b>2Q2011</b>    | <b>3Q2011</b>    | <b>4Q2011</b>    |
| Contract 1        |               |               |               |               | 584 000          | 92 000           | 92 000           | 92 000           | 140 000          |
| Contract 2        |               |               |               |               | 840 000          | 560 000          |                  |                  |                  |
| <b>Cumulated</b>  |               |               |               |               | <b>1 424 000</b> | <b>2 076 000</b> | <b>2 168 000</b> | <b>2 260 000</b> | <b>2 400 000</b> |

## ANNEX III - Description of Institutional Framework

### 3.1 Competent Authority

Under Action Point, MHSW has provided the skeleton structure of the foreseen document on administrative capacity in the field of tissue and cells (See figure 1.).

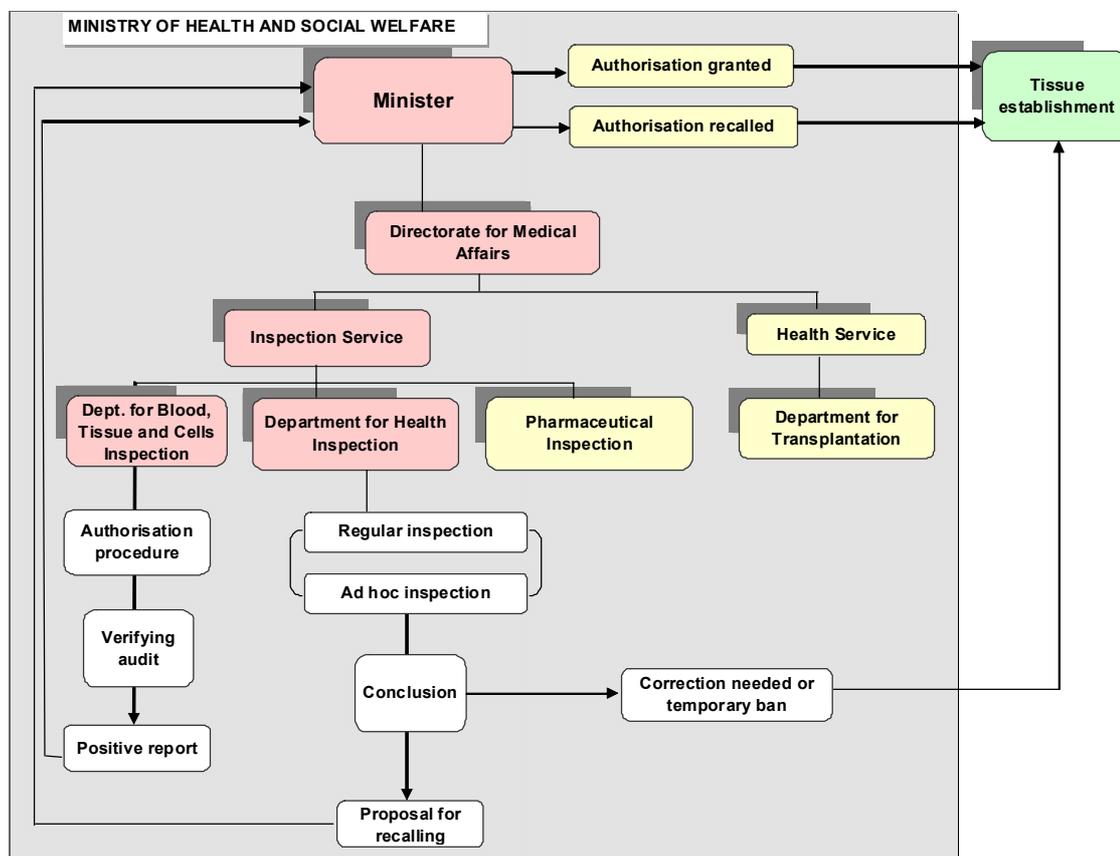


Figure 1. Blood, tissue and cells administrative capacity structure

There are two different technical units (departments) within the ministry, which are responsible for performing the tasks under the competence stated in accordance with the requirements of European Tissue and Blood Directives. The new one is: *Department for Inspection and Blood, Tissues and Cell Monitoring*, established for the purpose of authorisation procedures and other CA tasks (biovigilance, register...). The authorisation for tissue establishments is granted by the minister based on the positive report (after verifying audit). The other technical unit is the *Department for Health Inspection*, responsible for inspections of TE (regularly every 2 years and Extraordinary Inspections).

With the Ordinance on Amendments on Internal Structure of the Ministry of Health and Social Welfare that entered into effect on 22 January 2009, a systematisation of workplaces within the *Department for Inspection and Monitoring of Blood, Tissues and Cells* was realised: the number of employees, job descriptions and requirements for allocating to workplaces. The procedure for hiring new employees and filling in of foreseen workplaces within the Department (3 new employees) is done. Two persons have been hired and work in the Department for Inspection and Monitoring of Blood, Tissues and Cells since August 2009.

Following the employment of new employees within the Department for Inspection and Monitoring of Blood, Tissues and Cells, the attendance of new employees and health inspectors to professional training and education has been planned in regards to the auditing and inspections of tissue and cell establishments and implementation of other tasks within their stipulated competence. Education will be carried out in 2009 by using the TAIEX technical assistance within the framework of EC funded education programmes for tissues and cells (workshop for regulators is under preparation)

Further education and expertise are planned to be provided through the twinning component of this project.

### **3.2. Description of Institutional Framework of the Blood Transfusion**

The blood transfusion activity in Croatia is coordinated by MHSW. The advisory body of MHSW for transfusion medicine is the National Transfusion Commission.

#### Restructuring and rationalisation of the Transfusion service in Croatia

- The Plan of Reorganization of Transfusion Service in Croatia is in the process of adoption by the MHSW. This plan envisions the merger of smaller blood centres (21 to 9) leading to a new structure of nine (9) blood establishments for collection, processing and testing. Five of these nine blood centres should perform serological testing and two of the nine blood centres should perform NAT testing. (*Figure 2.*)
- Transfusion service will operate under a common framework of standard procedures and with a common information system. One essential element of this programme – the national computing system - has already been funded by the MHSW, the provider has been selected following tender, and the work at hand is aimed at having the system operational by the end of this year.
- The national blood policy is in the process of adoption by MHSW as well.

#### Current Situation:

##### Transfusion service

- In Croatia, there are 34 transfusion centres.
- CITM, located in Zagreb, is a main public establishment in the field of transfusion medicine and therefore is a Referral Centre for Transfusion Medicine of the MHSW. CITM represents the basic blood establishment centre responsible to coordinate, organize and verify the activities of the entire transfusion service at the country level, from promotion and collection to distribution of blood and blood components to hospital transfusion units. CITM organizes scientific research and transfusion medicine education. In addition, CITM has a reporting role in Croatian transfusion service and is responsible for collation, onward reporting, recalls and corrective measures. Since 2001. CITM has achieved and maintained the quality standards in accordance to ISO 9001/2000 (issued by Lloyd/UK). Every six months Lloyd's inspector carry out supervision in CITM, and every 4 years a full inspection for certification. Therefore CITM is enhanced to become the centre of excellence, training centre and reference model for other blood establishments in country.

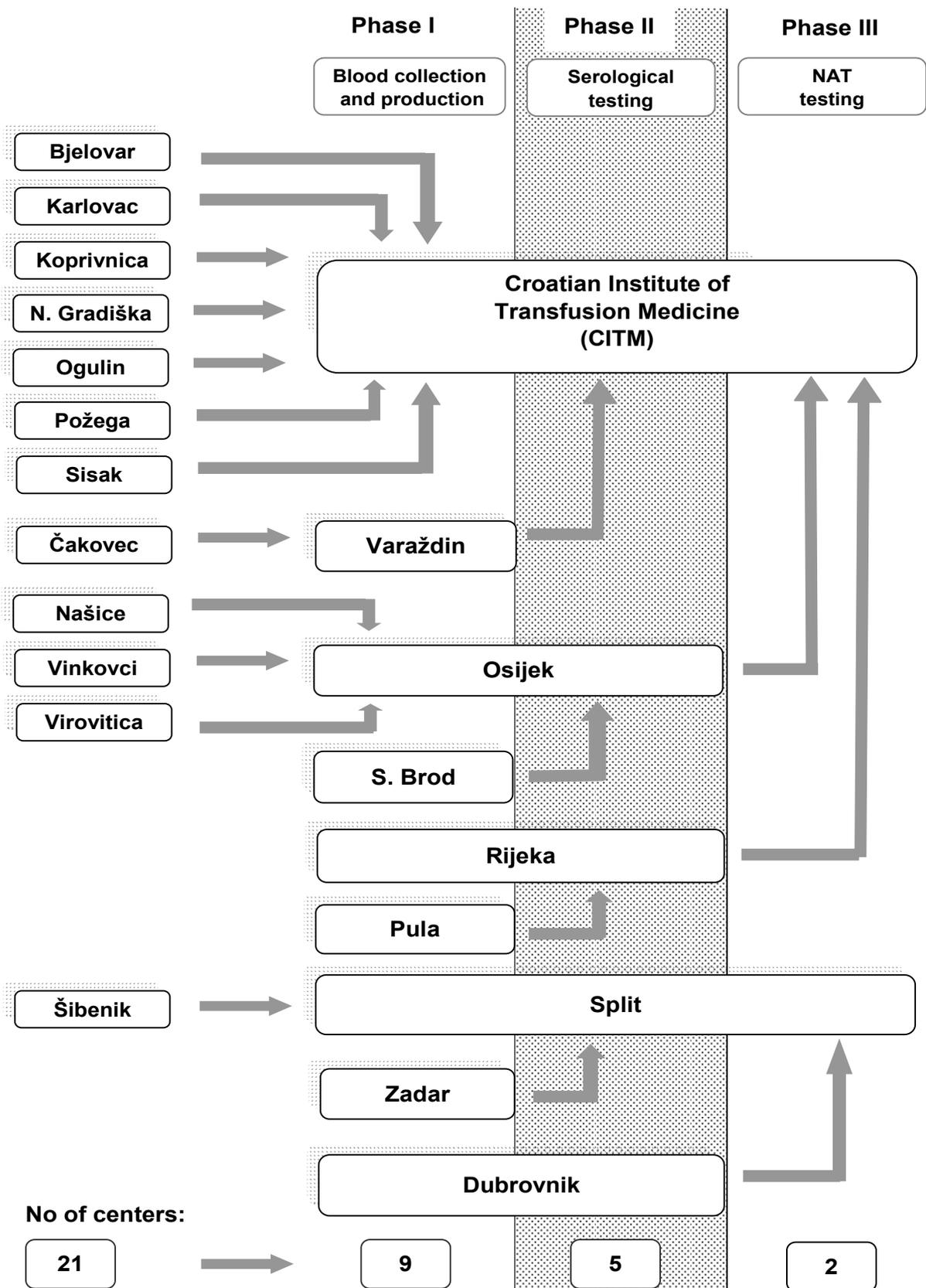


Figure 2. Plan of Reorganization of transfusion service

*Blood and blood products, transfusion transmitted infections*

- In Croatia, transfusion service collects a total of approximately 160.000 blood units *per year*. With 36 donations/1000 citizens, Croatia is sufficient in blood components, but not with plasma derivatives. Only 1.7% of these blood units are transfused as whole blood, whereas plasma is separated from the remaining 98.3% of blood units. Only 49% of the total amount of collected plasma by blood transfusion service or 75.759 units (approximately 20.000 L) are used for fractionation, whereas the rest is intended for transfusion
- Plasma for clinical use is not quarantined or leucodepleted. Frequency of whole blood donations is 1.7 donations/year/donor which is an organisational problem for quarantine of FFP as well as a lack of storage
- NAT testing of HIV, HBV and HCV infection is not performed at present in Croatia because the national informational system is not implemented yet.
- Cytomegalovirus (CMV) testing is not performed at present in Croatia. Incidence of CMV is over 85% in Croatian population.
- Leucodepletion in Croatia is performed in 69% of platelets and approximately 13% of red cells.
- Therefore, inactivation of pathogen in plasma should be a good possibility for additional reduction of the residual risk of transmission blood borne viruses

Residual risk of transfusion transmitted HIV, HBV and HCV infection in Croatian blood recipients was calculated on 45% of all donations collected (See Figure 3.). Calculated risk took into account incidence of seroconversions in regular/repeat donors as well as the window period, as a measure of serological test sensitivity.

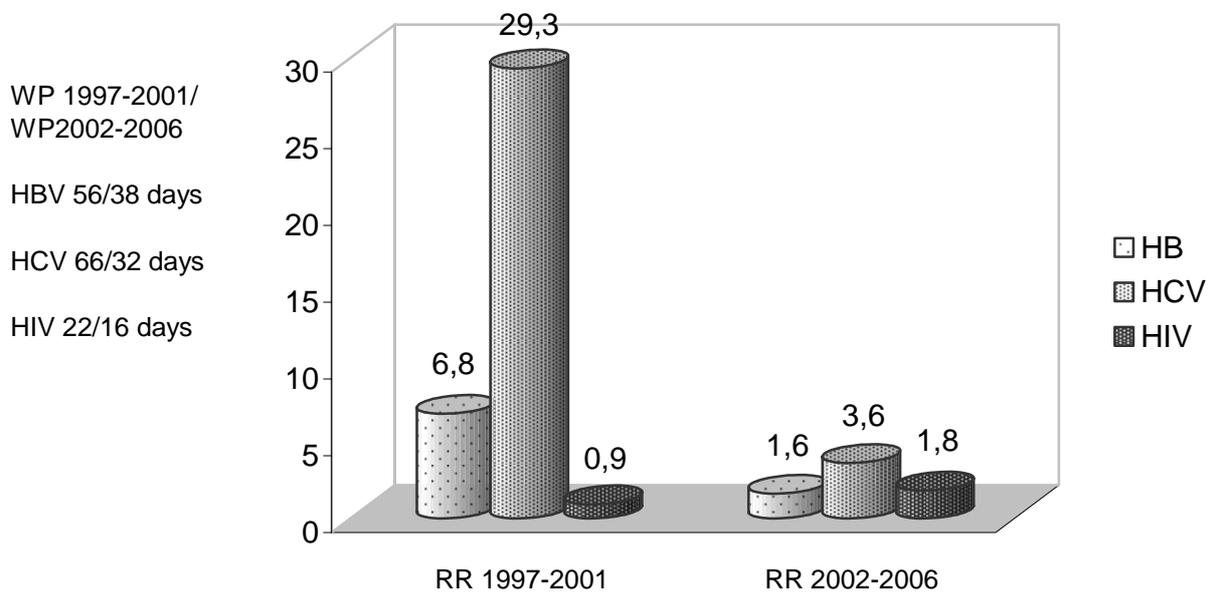


Figure 3. Residual risk of transfusion transmitted HIV, HBV and HCV infection in Croatia /10<sup>6</sup> doses

The Figure 3 represents the influence of test sensitivity (window period) on residual risk. To minimize the risk we have introduced ULTRA sensitive tests as Prism HBsAg, combo HCV or HCV Ag test and combo HIV test, which shortened window period and reduced residual risk (comparison of the results for period 1997–2001 and period 2002–2006).

### 3.3 Tissue and cells

Regarding the HSC, there are transplantation activities in 4 hospitals all located in Zagreb (University Hospital Centre Zagreb, University Hospital Merkur, University Hospital Dubrava and Children’s hospital Zagreb), with three autologous HSC banks and one cord blood bank included. Transplant centres perform approximately 140-160 HSC transplantations per year: in 2008 total number of HSC transplantation were 157 (130 autologous, 26 related and 1 unrelated transplant)

University Hospital Centre Zagreb is the most experienced hospital in HSC banking and transplantations in Croatia. An autologous stem cell bank was established in 1988 and to date at University Hospital Centre Zagreb more then 1000 auto-HSC have been performed. CBB was funded in 2007 with independent sources of funding (charity organization Ana Rukavina Foundation). This bank is the only CBB in Croatia and it is already organized as a national bank. To date, the CBB has collected more than 1000 donations of cord blood units, and at the beginning of 2009 started to report cord blood transplants to Bone Marrow Donors Worldwide (BMDW) through the Croatian Registry of Stem Cell Donors, which is located in same hospital. CBB is preparing for application for membership in the European/International network of cord blood banks with specific and mandatory quality management rules. Hospital development plans anticipate development of the CBB in the multi-tissue bank within next 3-5 years. Therefore, University Hospital Centre Zagreb started centralisation process to attain an objective of one multi-tissue bank consolidating all tissue and cells banking activities (bones, hematopoietic stem cells (HSC), ocular tissues and cord blood) (Figure 4.)

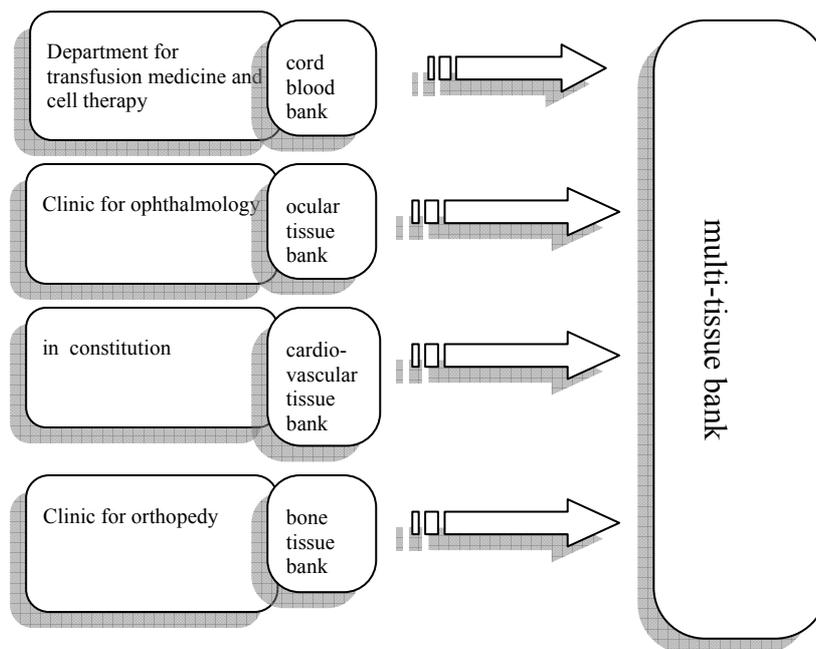


Figure 4. Proposal for tissue-banking centralisation

## **Annex IV: Reference to laws, regulations and strategic document**

### Reference list of relevant laws and regulations

- Act on blood and blood components OG 79/06 (EU Directive 2002/)
- Ordinance on certain technical requirements for blood and blood components OG 80/07 (EU Directive 2004/33)
- Ordinance on the quality assurance of blood and blood products in authorised healthcare institutions OG 80/07 (EU Directive 2005/62) OG 18/2009
- Ordinance on the system of the traceability of blood components and the monitoring of serious adverse events and serious adverse reactions OG 63/07 (EU Directive 2005/61) OG 18/2009
- Act on Explanation and Transplantation of Parts of the Human Body for Therapeutic Purposes OG 177/2004; OG 45/09
- Ordinance on measures to assure the safety and quality of parts of the human body for medical use OG 143/2005
- Ordinance on allocation procedure for allogenic unrelated haematopoietic stem cells and the operation of the register of potential bone marrow donors OG 151/2005
- Ordinance on method of co-operation with related foreign and international organisations in order to exchange organs or tissues for transplantation OG 141/2005
- Ordinance on method of filing medical documents on performed explanations and transplantations of parts of the human body OG 152/2005
- Ordinance on storage and transportation of parts of the human body intended for transplantation OG 152/2005
- Ordinance on work and supervision of health establishments or parts thereof with tissue banks OG 2/2005
- Ordinance on criteria for the allocation of parts of the human body and the method of keeping the national waiting list OG 152/2005
- Ordinance on the reporting procedure of the death of person eligible as donors of parts of the human body for therapeutically oriented transplantation OG 152/2005
- Ordinance on procedure for collection, storage and use of haematopoietic stem cells OG 59/2008
- Regulation on internal organisation of the Ministry of Health and Social Welfare, adopted on 29 December 2008 by the Government of the Republic Croatia (OG 2/2009)
- (EC) Assessment mission of services related to blood, tissues and cells in Croatia, held on 02-06 June 2008, Mission report
- Plan of activities necessary for the transposition and implementation of the aquis communitarian in the area of protection of health, Ministry of Health and Social welfare, Chapter 28 - Consumer and Health Protection , Zagreb, July 2008

- Commission Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells
- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
- Commission Directive 2002/98/EC of the European Parliament and of the Council of 7 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
- Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components
- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events
- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

### **Reference to Accession Partnership (AP)**

Accession Partnership document (2008/119/EC) with reference to paragraph „*Ability to assume the obligations of membership*“ within Chapter 28, identifies priorities in the field of Consumer and health protection which requires further alignment with the *acquis*, including in the areas of tissues and cells, and ensure adequate administrative structures and enforcement capacity.

According to Accession Partnership document (2008/119/EC) with reference to chapter 3. Priorities within paragraph “*Economic criteria*”, Croatia is also expected to continue implementation of comprehensive health care reforms to avoid the accumulation of new payments arrears in the health system and to improve efficiency of health spending (availability of blood, tissue and cells based on self-sufficiency).

### **Reference to National Programme for the Adoption of the Acquis (NPAA)**

The strategic document „National programme for the integration of the Republic of Croatia into the European Union - NPIEU”, May 2008 within Chapter 28 (Consumer and health protection), in the paragraph B) Key Priorities placing priorities on the field of blood and blood components, tissue and cells.

The main objectives are strengthening of administrative capacity for assurance of proper implementation of aligned laws and related subordinate legislation in the area of blood

and blood components, tissue and cells (accreditation of blood collection establishments and tissues and cells, provision of technical conditions).

### **Reference to Multi-Annual Indicative Financial Framework (MIPD)**

Multi-annual indicative planning document clearly indicates in chapter Strategic objectives under IPA Component I, paragraph 2.2.2. “*Strategic choices for IPA assistance over the period 2008-2010*”, to set measures for building capacity for transposition and implementation according to competence criteria by assumed liability from EU membership, in respect of which this project relates.

## **ANNEX V- Details per EU funded contract (\*) where applicable:**

### **5.1. Contract: Twinning**

The project will be implemented in the form of a Twinning contract between Croatia and a Member State/Member States. The project duration is described in the 5. Indicative Implementation schedule (periods broken down per quarter). The Twinning partner(s) will manage all aspects of execution in close cooperation with the MHSW.

The Twinning partner(s) will provide two Resident Twinning Advisors (RTA) and also secure a pool of short-term experts (STE), who will be called upon whenever necessary to contribute to the achievement of the mandatory results and especially for the purpose of advisory services and training according to the work plan that will be prepared as part of the corresponding contract.

The EU Twinning advisors will work together with the staff of the beneficiary institution under the overall direction of the beneficiary institution(s) and the Project Steering Committee.

The EU Twinning partner will be a Member State institution directly involved in blood/tissue and cells sectors covered within the project. Member States may also form a consortium which could result in a wide range of qualified senior experts gathered from public administrations or mandated bodies from up to two Member States, provided that national approaches can be harmonized within this consortium.

### **Expert inputs:**

#### **1. Project Leader (PL):**

The PL should be a high ranking official with broad knowledge of all processes that the project deals with, who will continue to work at his/her Member State administration but devote, some of his/her time to conceive, supervise and co-ordinate the overall thrust of the Twinning project.

The PL will allocate a minimum of 3 days per month including one visit every 3 months (more for complex projects) to Croatia as long the project lasts.

a) Qualifications:

- Broad long-term knowledge of all processes in the area of *acquis* the project is dealing with;
- High-ranking official, commensurate with an operational dialogue at vice-ministerial level;
- Overall appreciation of the problems and solutions in the sector;
- Capable of unblocking any problems at highest level;
- Good leadership skills,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2.,
- Experience in project management.
- Active knowledge of English language,
- Advanced computer skills.

b) Tasks:

- Overall project co-ordination,
- Co-chairing, with the Croatian PL, the regular project implementation steering committee meetings,
- Mobilizing short- and medium term experts,
- Executing administrative issues (i.e. signing reports, administrative order etc.),
- Ensuring backstopping and financial management of the project in the MS.

**2. Resident Twinning Advisor (RTA):**

Profile of the Resident Twinning Adviser

The project needs to be provided with two RTA-s (one for blood, and the other for tissues and cells) that will be present at the Ministry simultaneously, each for a period of 12 months.

Requirements:

*1. Resident Twinning Advisor for tissue and cells (RTA):*

a) RTA background

RTA expert will provide advice through technical assistance to the MHSW in setting up work of Department for inspection and monitoring, tissue and cells and its fully operations. Expert will be located at the MHSW, Zagreb in the Directorate for Medical Affairs. He/she will also work in other stakeholder institutions as necessary. He/she should be a person with significant experience as a manager and should have a capacity for initiating new projects. Experience of working outside of the home country administration would be an advantage. In addition to the short term experts, he/she will also occasionally work together with the MHSW to provide inputs focused on:

- Licensing system tissue and cells,
- Facilitation of transferral of EU member states best practices and developing potential for their implementation in the work of CA,
- Inspection and control measures,
- Biovigilance system (vigilance and surveillance of tissue and cells) quality system,
- Training programmes in the field of tissue and cells.

The RTA must be highly qualified in tissue and cells banking, in general and the field of

quality management in particular covered by the twinning covenant, and must possess good management skills. Experience with the operation of pre-accession programmes would be a comparative advantage.

#### b) RTA qualifications

- Minimum of 10 years experience in the organization of the practical application of the tissue and cells banking at managerial/expert level,
- Familiar with tissue and cells field in a European Union Member State with particular emphasis on institutional set-up and implementation (preferably a comparative knowledge of other Member States systems),
- Experience in project management,
- Experience in the participation of a legislative process/law drafting,
- Broad international contacts/exposure will be an asset,
- Advanced university degree (medical doctor is preferable),
- Strong written, oral and inter-personal communication skills in English,
- Good communication skills and experience in developing, co-coordinating and conducting training programmes,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2.,
- Experience in managing a large team of experts.

Assets: Experience in working in a different cultural environment

#### Tasks of the Resident Twinning Adviser:

- Designing a work plan for the implementation of the programme and to assist the process of drawing up a covenant,
- Assisting the preparation of all strategic project documents (inception study, sector strategy/policy/plan, quarterly monitoring reports, final project report, training manuals etc.)
- Ensuring continuity of implementation through: the execution of the day to day management; working on a daily basis with the MHSW staff to implement the project,
- Planning and coordinate outputs,
- Together with the PL: nominating, mobilizing, coordinating and supervising STE,
- Coordinating and organizing study visits, training activities, workshops,
- Together with STE preparing and producing all training materials,
- Ensuring proper quality of outputs,
- Providing detailed reports on the impact of the project,
- Promoting the Service to major stakeholders through presentations, workshops and seminars.

### *2. Resident Twinning Advisor for blood (RTA)*

#### a) RTA background

A RTA expert will provide advice through technical assistance to the MHSW in setting up work of Department for blood inspection and monitoring and its fully operations. Expert will be located at the MHSW, Zagreb in the Directorate for Medical Affairs. He/she will also work in other stakeholder institutions as necessary. He/she should be a person with significant experience as a manager and should have a capacity for initiating new projects. Experience of working outside of the home country administration would be an advantage. In addition to the short term experts, he/she will also occasionally work together with the

MHSW to provide inputs focused on:

- Licensing system for blood,
- Facilitation of transferral of EU member states best practices and developing potential for their implementation in the work of CA,
- Inspection and control measures,
- Haemovigilance system ( vigilance and surveillance of blood),
- Blood quality system,
- Training programmes in the field of blood.

The RTA must be highly qualified in transfusion field, in general and the field of blood quality management in particular covered by the twinning covenant, and must possess good management skills. Experience with the operation of pre-accession programmes would be a comparative advantage.

#### b) RTA qualifications

Minimum of 10 years experience in the organization of the practical application of the transfusion at managerial/expert level;

- Familiar with blood services and different model in a European Union Member State with particular emphasis on institutional set-up and implementation (preferably a comparative knowledge of other Member States systems),
- Experience in project management,
- Experience in the participation of a legislative process/law drafting,
- Broad international contacts/exposure will be an asset,
- Advanced university degree (medical doctor is preferable),
- Strong written, oral and inter-personal communication skills in English,
- Good communication skills and experience in developing, co-coordinating and conducting training programmes,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2.,
- Experience in managing a large team of experts.

Assets: Experience in working in a different cultural environment

RTA tasks and responsibility:

- Designing a work plan for the implementation of the programme and to assist the process of drawing up a covenant,
- Assisting in the preparation of all strategic project documents (inception study, sector strategy/policy/plan, quarterly monitoring reports, final project report, training manuals etc.),
- Ensuring continuity of implementation through: the execution of the day to day management; working on a daily basis with the MHSW staff to implement the project,
- Planning and coordinating outputs,
- Together with the PL: nominating, mobilizing, coordinating and supervising STE,
- Coordinating and organizing study visits, training activities and workshops,
- Together with STE to preparing and producing all training materials,
- Ensuring proper quality of outputs,
- Providing detailed reports on the impact of the project,
- Promoting the Service to major stakeholders through presentations, workshops and seminars.

### 3. Short-term experts (STE)

Profile of the Short-term experts

Requirements:

*1. STE 1: short-term experts for blood banking include quality management in this field*

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,
- Advanced university degree in a relevant subject,
- Appropriate experience in quality management system in blood banking,
- Familiar with EU regulation and guidelines,
- Fluent knowledge of English,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group,
- Providing trainings and trainings material in corporation with RTA.

*2. STE 2: short-term experts for plasma inactivation procedure*

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,
- Advanced university degree in a relevant subject,
- Experience in implementation of virus inactivation of FFP in blood bank and on national level,
- Familiar with EU regulation and guidelines,
- Fluent knowledge of English,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group,
- Providing trainings and trainings material in corporation with RTA.

*3. STE 3: short-term experts in tissue banking include quality management in this field*

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,

- Advanced university degree in a relevant subject (medical doctor is preferable),
- Appropriate experience in tissue processing and quality management system in tissue banking,
- Familiar with EU regulation and standards of European professional organization,
- Fluent knowledge of English,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group,
- Providing trainings and trainings material in corporation with RTA.

*4. STE 4: short-term experts for the cord blood banking include quality management in this field*

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,
- Advanced university degree in a relevant subject (medical doctor is preferable),
- Appropriate experience in cord blood banking and quality management system in tissue banking,
- Familiar with EU regulation and standards of European professional organization (NetCord-FACT and JACIE),
- Fluent knowledge of English,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group,
- Providing trainings and trainings material in corporation with RTA.

*5. STE 5: short-term experts for reproductive tissue and cells*

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,
- Advanced university degree in a relevant subject (medical doctor is preferable),
- Appropriate experience in banking of reproductive tissue and cells,
- Familiar with EU regulation on that issues,
- Fluent knowledge of English,

- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group.

#### 6. STE 6: short-term experts for licensing and inspection of blood, tissue and cells

a) Experts' qualifications:

- Minimum of 5 years professional experience in relevant field,
- Advanced university degree in a relevant subject (medical doctor is preferable),
- Knowledge of different organization models of competent authority across Europe,
- Experience in licensing, inspection and control measures for blood, tissue and cells,
- Experience in organization of biovigilance system at national level for blood, tissue and cells,
- Knowledge in designing and implementation of common coding system for traceability purposes,
- Good written and oral command of English,
- Proven contractual relation to public administration or mandated body, as defined under Twinning manual 5.3.2,
- Capacity to integrate into a large expert team,
- Willingness to work in a different cultural environment.

Assets: Experience in working in a different cultural environment

b) Experts' tasks and responsibility:

- Participating in specific working group,
- Providing trainings and trainings material ,in corporation with RTA, for all professionals,
- Delivering the selected training modules, in coordination with RTA, to the Competent Authority's officers.

### 5.2 Contract: Supply contract

Investment will be focused on:

In field of blood bank:

1. to improve immunohaematology testing of blood donors
2. increasing quality an safety of FFP

In the field of tissue and cells- cord blood bank:

3. establishing laboratory for quality control of tissue and cells
4. increasing storage capacity which will enable storage of different types of tissues for clinical uses.

### 5.2.1. Present laboratory equipment in blood establishment (CITM)

| Equipment (description)              | Quantity (in pieces) |
|--------------------------------------|----------------------|
| A C L ELITE PRO ANALIZATOR IL        | 1                    |
| AGGREGOMETER - IMPACT-R-DIAMED       | 1                    |
| AGITATING BALANCE - OPTIMIX PLUS     | 18                   |
| PLASMA FREEZER - REVCO               | 1                    |
| ARCHITEKT I 2000                     | 1                    |
| AUTO-LIPA                            | 1                    |
| BACT/ALERT                           | 1                    |
| BIOFUGE 15R                          | 1                    |
| CELL SEPARATOR - AMICUS              | 2                    |
| CELL SEPARATOR - AUTO-C              | 2                    |
| CELL SEPARATOR - HAEMONETICS MCS+    | 3                    |
| CELL-DYN 3200 ABBOTT                 | 1                    |
| BLOOD CRYOCENTRIFUGE                 | 5                    |
| LABORAT. CENTRIFUGE                  | 30                   |
| COAGULATOR - TEHNOCHROM IV PLUS      | 1                    |
| COBAS AMPLICOR II                    | 1                    |
| COBAS AMPLIPREP                      | 1                    |
| COBAS TAQMAN 48                      | 1                    |
| DUOMAX 1030                          | 1                    |
| DYNAMICAL INKUBATOR - ABBOTT         | 1                    |
| REFRIGERATORS +4° C                  | 25                   |
| FREEZERS -20° C - -80° C             | 10                   |
| EVOLIS BIO – RAD                     | 1                    |
| FOTOMETAR - SPECTRA                  | 2                    |
| PLASMA FREEZER - REVCO               | 1                    |
| HAMILTON MIKRO LAB AT 2 PLUS PIPETOR | 2                    |
| HEMOCUE PLASMA/LOW HB                | 2                    |

|                                       |    |
|---------------------------------------|----|
| ID – PIPETOR MP – 1 004736 / 5-25 ML. | 1  |
| LAMINAR-FLOW                          | 4  |
| MAGNA PURE COMPACT                    | 1  |
| MICROSCOPE FLUORESCENT                | 2  |
| MINI VIDAS                            | 1  |
| MULTIPLATE 5.0 ANALYZER               | 1  |
| MULTISEGMENTACION SIELER - MS 970 E   | 1  |
| OPTIPRESS II                          | 11 |
| PCR EPPENDORF MASTERCYCLER            | 1  |
| PCR INSTRUMENT 9700                   | 1  |
| PCR INSTRUMENT ABI 2700               | 1  |
| 7500 REAL TIME PCR SYSTEM             | 1  |
| PLASMATHERM                           | 3  |
| PRYSM ANALIZATOR                      | 1  |
| SEGMENTATION SYSTEM - SARSTEDT        | 1  |
| SEQUENCER ABI 310                     | 1  |
| SLT PROFIBLOT                         | 1  |
| SSA SAFE SAMPLING AUTOMATE            | 1  |
| STERILE CONNECTION DEVICE - COMPODOCK | 7  |
| SUMMIT PROCESSOR                      | 1  |
| SWING – TWIN SAMPLER                  | 3  |
| TANGO-OPTIMO                          | 2  |
| TECAN (GENESIS)                       | 1  |
| TROMBOCITE AGITATOR                   | 3  |
| WALK-IN CHAMBER (+4 <sup>o</sup> C)   | 1  |

### 5.2.2. Laboratory equipment needed for blood establishment (CITM) – indicative list

| Equipment (description)  | Quantity (in pieces) | EUR (for all pieces) |
|--|----------------------|----------------------|
| 1. Automated system for blood group serology testing   | 1                    | 466 000              |
| 2. Blood irradiator  | 1                    | 144 124              |
| 3. Centrifuge for blood bags   | 4                    | 150 000              |
| 4. Fresh frozen plasma freezer   | 2                    | 128 110              |
| 5. Plasma inactivation system  | 1                    | 68 000               |
| 6. Flow cytometer  | 1                    | 130 000              |
| 7. Centralised and computerized temperature monitoring and data logging system for freezers/refrigerator temperature | 1                    | 16 014               |
| 8. Automated segmentation system with 7 sealing heads  | 2                    | 24 021               |
| 9. Automated microbial detection system for blood components   | 1                    | 48 041               |
| 10. Walk-in chamber (-40° C, 100 m <sup>2</sup> )  | 1                    | 144 124              |
| 11. Walk-in chamber (-40° C, 30 m <sup>2</sup> ), quarantine   | 1                    | 32 027               |
| 12. Walk-in chamber (+4° C, 20m <sup>2</sup> ), blood components quarantine and storage                              | 2                    | 32 027               |
| 13. Refrigerator for blood donor samples archive ( -80° C)   | 2                    | 40 035               |
| 14. Automated centrifuge and separator integration system (TACSI)  | 1                    | 140 000              |
| <b>TOTAL</b>   |                      | 1 562 523            |

### 5.2.3. Laboratory equipment needed for tissue and cells- cord blood bank – indicative list

| Equipment (description)   | Quantity (in pieces) | EUR (for all pieces) |
|---|----------------------|----------------------|
| 1. Automated flow cytometer four-color, dual-laser, capable of both cell analysis and sorting                               | 1                    | 115 292              |
| 2. Cell counter with providing differential leukocyte including haematopoietic progenitor cell and nucleated red blood cell | 1                    | 48 481               |

|  |   |                  |
|--|---|------------------|
| 3. Cell CO <sub>2</sub> incubator with fungicidal/bactericidal solid copper interior   | 3 | 31 433           |
| 4. Phase microscope with camera and software   | 1 | 14 264           |
| 5. Storage container for liquid nitrogen capacity 400 L equipped for cryo bags (250ml) with data logger compatible with existing management system                 | 6 | 214 750          |
| 6. Storage container for liquid nitrogen capacity 400 L equipped for cryo bags (25ml) with data logger compatible with existing management system                  | 1 | 41 182           |
| 7. Storage container for vapour phase of liquid nitrogen capacity 400 L equipped for cryo bags (100ml) with data logger compatible with existing management system | 3 | 108 325          |
| 8. LN <sub>2</sub> stainless steel vertical tank with fixed integrated withdrawal system, installed line 200 cm and T-connector                                    | 4 | 30 667           |
| 9. Transport dry shipper for cryo bags with data logger  | 3 | 19 971           |
| 10. Ultra freezer capacity 700 L (-80 °C)  | 7 | 125 890          |
| 11. Laboratory cell processing device with coolmix and traceability software   | 1 | 67 356           |
| 12. Centrifuge for tubes and microtitar plates   | 2 | 12 000           |
| 13. Sealer suitable for sealing of EVA and aluminium freezing bags with sealer foot pad  | 4 | 25 000           |
| 14. Medical vacuum sealer with sealer foot pad   | 2 | 20 000           |
| 15. Automated liquid nitrogen storage system for cord blood  | 1 | 380 000          |
| <b>TOTAL</b>   |   | <b>1 290 611</b> |

#### 5.2.4. Laboratory equipment for blood, tissue and cells covered by project – indicative list

**Table: Purchasing new laboratory equipment**

| Equipment (description)                              | Quantity (in pieces ) | EUR (for all pieces) |
|--|-----------------------|----------------------|
| 1. Automated system for blood group serology testing | 1                     | 465 124              |
| 2. Plasma inactivation system                        | 2                     | 135 156              |
| 3. Fresh frozen plasma freezer                       | 1                     | 59 403               |

|   |   |                  |
|---|---|------------------|
| 4. Blood cryofuge centrifuge with computer data system  | 1 | 37 327           |
| 5. Automated flow cytometer four-color, dual-laser, capable of both cell analysis and sorting   | 1 | 115 292          |
| 6. Cell counter with providing differential leukocyte including haematopoietic progenitor cell and nucleated red blood cell                                       | 1 | 48 481           |
| 7. Cell CO <sub>2</sub> incubator with fungicidal/bactericidal solid interior   | 2 | 20 962           |
| 8. Inverted microscope equipped with digital camera, computer and analysis software   | 1 | 14 264           |
| 9. Storage container for liquid nitrogen capacity 400 L equipped for cryo bags (250ml) with data logger compatible with existing management system                | 5 | 178 958          |
| 10. Storage container for liquid nitrogen capacity 400 L equipped for cryo bags (25ml) with data logger compatible with existing management system                | 1 | 41 182           |
| 11. Storage container for vapour faze of liquid nitrogen capacity 400L equipped for cryo bags (100ml) with data logger compatible with existing management system | 2 | 72 216           |
| 12. LN2 stainless steel vertical tank with fixed integrated withdrawal system, installed line 200 cm and T-connector  | 2 | 19 376           |
| 13. Transport dry shipper for cryo bags with data logger  | 2 | 1 314            |
| 14. Ultra freezer capacity 700 L (-80° C)   | 6 | 107 905          |
| 15. Laboratory cell processing device with coolmix and traceability software  | 1 | 67 356           |
| <b>TOTAL</b>  |   | <b>1 396 313</b> |

**Need of derogation to PRAG :**

**Specification of equipment:** Automated system for blood group serology testing Olympus PK7300 is produced only by Olympus / Japan. Olympus d.o.o. Zagreb is exclusive importer for Croatia.

**Justification:**

Fully automated system is necessary for blood group serology testing. System that completely satisfies our needs is produced by Olympus (Japan) only. There is no other manufacturer of such a high processing speed and low running cost laboratory equipment. The 2nd similar system on the market is the Galileo from Immucor (USA). Its speed is under real-life conditions below 100 samples in hour, which is to low capacity for our routine work.

It is very important that blood group serology (ABO, RhD, RH antigens, Kell typing, red blood antibody screening and high titre of anti-A and anti-B) is performed on system

which is fully front-end-laboratory automated. At the present, in CITM blood group serology is performed with pipeting system Genesis RSP 200 (10 years old) and automated blood grouping equipment Tango Optimo (1 year old) for irregular antibody screening of blood donors, patients and pregnant women. It is also important to point out that with present equipment the titter of anti-A or anti-B antibodies present in plasma of 0 blood groups can not be tested. 0 blood group red blood cells and platelets can be transfused to patients of any ABO group but the transfusion can be complicated as post transfusion haemolytic reaction due the action of anti-A and anti-B present in plasma. These haemolytic reactions may be prevented by screening and excluding high titre anti-A or anti-B donors. Introduction of Olympus blood group analyzer will significant improve the quality of our plasma and platelets blood products.

Olympus blood group analyzer PK 7300 is laboratory equipment that will be used in blood group serology for testing of 400 to 500 donor's blood samples per day. It has loading capacity of 300 samples and a possibility of using in-house produced reagents. These reagents can be highly diluted which ends in very low running costs as well. Based on evaluation that has been made at the University hospital Charite in Berlin we made theoretical calculation, which shows a dramatic decrease in running costs of blood donor testing, by implementation of Olympus PK 7300. For the reagent price of one (1) test performed with present technique, we shall have possibility to perform 240 tests by Olympus.