

**Standard Summary Project Fiche – IPA decentralised National programmes**  
**(Maximum 12/15 pages without the annexes)**

**1. Basic information**

- 1.1 CRIS Number: TR2009/0328.02
- 1.2 Title: Alignment in Human Tissues and Cells
- 1.3 Sector: ELARG Statistical code: 03.28 Consumer and Health Protection.
- 1.4 Location: Ankara, Turkey

**Implementing arrangements:**

1.5 Implementing Agency:  
Central Finance and Contracting Unit  
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Ankara / TURKEY

1.6 Beneficiary (including details of SPO): Ministry of Health of Turkey, Curative Services Directorate General, Tissue and Cell Transplantation Services Office

**SPO:** Dr. Zeynep Zehra Coşkun (M.D) (Head of Tissue and Cell Transplantation Services Unit)  
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**Financing:**

- 1.7 Overall cost (VAT excluded)<sup>1</sup>:  
3.000.000 €
- 1.8 EU contribution:  
2.700.000 €
- 1.9 Final date for contracting:  
2 years after signing the Financing Agreement
- 1.10 Final date for execution of contracts:  
2 years after the last date of contracting deadline
- 1.11 1 year after the end date for the execution of contracts

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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)

## 2. Overall Objective and Project Purpose

### 2.1 Overall Objective:

To contribute to the efforts of Government of Turkey, towards ensuring the safety and quality of human tissues and cells from donor to patient, in line with the EU legislation.

### 2.2 Project purpose:

To improve quality of haematopoietic stem cell transplantation treatment and studies and align with *Acquis*.

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

Link with AP: Council Decision of 18 February 2008 on the principles, priorities and conditions contained in the Accession Partnership with the Republic of Turkey and repealing Decision 2006/35/EC (2008/157/EC) requires further alignment with the consumer and health acquis, including in the areas of blood, tissues and cells and adequate administrative structures and enforcement capacity.

Link with NPAA:

(TR) Council of Ministers Decision No: 2008/14481 Dated 10/11/2008 on 2008 National Programme for the Adoption of the Acquis is published in the Official Gazette of the Republic of Turkey dated 31 December 2008 numbered 27097.

Priority 28.2 Further align with the health acquis and ensuring adequate administrative structures and enforcement capacity

#### 1 Schedule of legislative alignment

Table 28.2.1

Law on the Organ, Tissue and Cell Transplantation Services” will be published in 2009-2010.

Implementing Regulation on Tissue and Cell will be published in 2010.

#### 2 Schedule of institutional capacity building requirements necessary for legislative approximation and implementation

Table 28.2.2

Requirement no:7

Establishing of national hemotopathic stem cell coordination centre, voluntary donor centres, establishing of national sample collection centre, establishing of national tissue information bank, establishing of national cord blood collection centre, establishing of cord blood banks, opening new bone marrow trasplantation centres, establishing of national patient information bank and waiting list, establishing social service and national patient consultation units for patients in bone marrow trasplantation centres, increasing the number of regional tissue typing laboratories, etc.

## 2.4 Link with MIPD:

In Multi-annual Indicative Planning Document (MIPD) 2008-2010 for Turkey, in Component I-Transition Assistance and Institution Building, it is referred that "In addition to the above priorities, Institution Building support may also be provided in the following areas of the acquis, with more modest budgetary allocations: [...] Health Policy [...]".

## 2.5 Link with National Development Plan (where applicable):

In the 9<sup>th</sup> National Development Plan 2007-2013, Chapter 5 addresses the Economic and Social Developments in Turkey. Under subtitle 5.4. Strengthening Human Development and Social Solidarity, 5.4.2. Making the Health System Effective, states that by the year 2013 infrastructure, human resources and quality of the services are going to be raised in order to fulfill the requirements of the Plan. This Project is going to contribute to the efforts of Government foreseen in the National Development Plan.

## 2.6 Link with national/ sectoral investment plans (where applicable):

This project will be an important part of TÜRKÖK plan. Ministry of Health of Turkey invested on the physical infrastructure of TÜRKÖK and established the coordination unit fully equipped in **Dr. Ahmet Andıçen Ankara Oncology Training and Research Hospital** which will be the center of operations. By the end of 2009 MoH will be establishing 200 voluntary donor centers in 27 regions which will be funded by the national budget.

## 3. Description of project

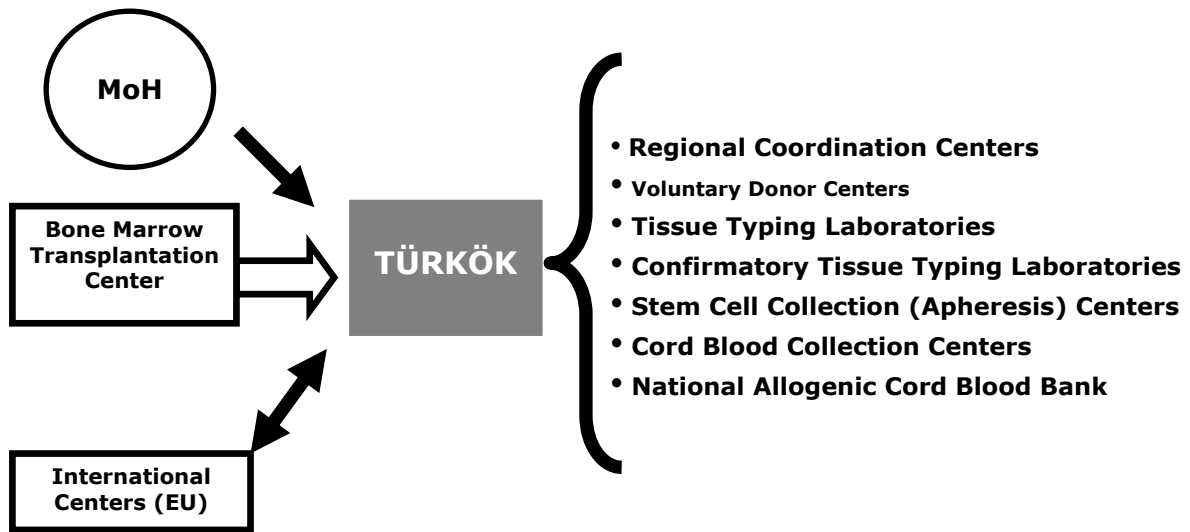
### 3.1 Background and justification:

The conclusions of the Helsinki European Council in December 1999 recognized Turkey as a candidate for membership to the European Union. In December 2004, the European Council concluded that Turkey sufficiently fulfils the Copenhagen political criteria to open accession negotiations. Accordingly the accession negotiations started on 3 October 2005. Following the analytical examination of Turkish legislation (screening process), the negotiations on Chapter 28: Consumer Protection and Health were opened in December 2007.

One of the closing benchmarks for Chapter 28 is related with the adoption of EU legislation concerning tissues and cells and ensuring adequate capacity for implementation.

With a view to aligning with the EU acquis on tissues and cells Tissue and Cell Transplantation Services will be adopted in 2009-2010 period. The legislation will regulate the procedures and the principles of supply, donation, procurement, testing, processing, preservation, storage, transportation, distribution, implantation and transplantation of organs, tissues, cells, stem cells and cell components for treatment, diagnostic or scientific purposes, and of other procedures relating to such activities. In addition, the Implementing Regulation on Tissue and Cell to be adopted in 2010 will set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and traceability requirements, notification of serious adverse reactions and events and coding of human tissues and cells.

## TÜRKÖK WORK FLOW



Today, hematopoietic stem cell transplantation centers can perform 45% of their potential. Existing Hematopoietic Stem cell transplantation centers suffers the lack of regular data flow and lack of organization and coordination between centers creates a problematic situation. At these centers quality control, standardization and international accreditation are not sufficient. Transplantation indications are not standardized. Distribution of transplantation centers does not fulfill the needs of the country. There are approximately about 2000–3000 patients waiting for hematopoietic stem cell transplantation. The number of registered tissue donors is 7.000 in Ankara and 30.000 in İstanbul University Hospitals. This number is 12.000.000 in Bone Marrow Donors Worldwide database so number for Turkey is lacking. There is a need of raising public awareness in this field.

As regards implementation, TÜRKÖK (Turkish Cell Coordination Center) will be set up in 2009. TÜRKÖK will be responsible for the management of the Tissue and Cell Treatment Coordination and Supervision System. Thus, it will be a bridge between patients waiting for allogenic hematopoietic stem cell transplantation and voluntary donors. Currently, there are no volunteer donor centres. Within the scope of Health Transformation Programme 200 donor centers will be set up in alt least 27 regions until the last quarter of 2009. These centres will work in coordination with TÜRKÖK.

There are also blood donation centers of Turkish Red Crescent Society. After the establishment of TÜRKÖK these centers are also planned to be in coordination with other donation centers.

Currently, there are 5 autologous cord blood banks in Turkey. A national allogenic cord blood bank will be established by last quarter of 2009.

The current number of transplantations is 10 per million and the aim is to increase this number to 60 per million. In this respect, the number of volunteer donors will be increased to 3000 per million via the 27 volunteer donor centres and the national allogenic cord blood bank. As a result, approximately 1 million donor pools will be established and the need for the bone marrow in Turkey in particular will be met (nearly 4000 transplantation annually). This structure will also serve the needs of the patients in need of bone marrow in the EU and other

countries. Following the completion of the data base of TÜRKÖK mutual exchange of donors between Turkey and the EU countries will be ensured.

Concerning the laboratories, there are 2 EFI (European Federation for Immunogenetics) accredited tissue typing laboratory. The number of tissue typing laboratories will be increased to 27. Additionally, in order to be accredited, it is essential to apply certain standards such as JACIE (Joint Accreditation Committee) and WMDA (The World Marrow Donor Association) in the field of bone marrow, EFI and ASHI in tissue typing laboratories and NetCord and Fact in the cord blood banking.

By aligning with the EU legislation, training personnel working at bone marrow transplantation centers, tissue typing laboratories, National Tissue Data Bank, National Allogenic Cord Blood Bank, Voluntary Donor Centers and Public Apheresis Center and adopting EU and international standards in laboratories, Turkey will be able to improve its implementations concerning tissues and cells, which in return will be a further step for fulfilling the benchmarks of Chapter 28.

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

#### Project impact:

The project is expected to produce three outcomes:

- i) Alignment of Turkish legislation on tissues and cells with the EU acquis.
- ii) Improving the administrative capacity of the relevant units of the Ministry of Health through trainings, and fulfilling the requirements for the accreditation of tissue and cell laboratories.
- iii) Establishing donor pools by strengthening the data collection system.

#### Catalytic impact:

The long-term catalytic effect will be the increase in the number of donors and providing high quality services to an increased number of patients. Accordingly, the number of the people in the waiting lists will diminish and the living period and quality for the patients receiving transplantations will improve. It will be possible to establish coordination with the EU with a view to serving the needs of the patients of both parties.

#### Its sustainability:

The system to be established within the scope of this project will be a part of the national coordination system. It shall continue its activities through its revolving fund and the share it obtains from the national budget. The project as a whole will have positive economical, psychological and social effects, in particular for bone marrow disease patients as well as their families and acquaintances. With the advancements in science, stem cell and cellular therapies will have wider implementations.

Cross Border Impact:

With the completion of the data base of TÜRKÖK, mutual exchange of donors between Turkey and the EU countries will be possible.

3.3 Results and measurable indicators:

Result 1. Legislation on tissues and cells are aligned with the EU.

OVI: Services on Tissues and Cells are operating according to the provisions of the Legislation adopted by the 1<sup>st</sup> quarter of 2011.

Result 2. Administrative capacity of personnel working at tissue data bank, voluntary donor centers and cord blood banks improved.

OVI: Treatment rate rose from %25 to %60. Bed occupation rose from %45 to %60 by the end of the implementation of the Project.

Result 3. Data collection system established.

OVI: National waiting patient list lowered to 100 patients.

Result 4. International standards attained for bone marrow centers, tissue typing laboratories, and cord blood banks.

OVI: 5 bone marrow transplantation centers, 5 tissue typing laboratories and 2 cord blood bank are operating with accreditation.

3.4 Activities:

Turkish Ministry of Health, Directorate General for Curative Services will provide the national co-financing for the project which will be €300,000.

The activities will be achieved under a service contract. These activities will focus on increasing the *acquis* implementation capacity of Ministry of Health.

Details of the project activities are as follows:

Activity 1. Alignment with EU Tissue and Cell Legislation

1.1. Turkish legislation revised (experts committee meetings)

1.2. Draft legislation in line with the EU *acquis* prepared. (experts committee meetings)

1.3. Guidelines for cell collection, processing, production and banking facilities prepared.

Means: Service Contract

Activity 2. Improving the administrative capacity of Ministry of Health

2.1. Curricula and 6 modules for training; bone marrow, tissue typing lab, tissue data bank, allogenic cord blood collection centers, voluntary donor centers and public apheresis centers prepared and published.

2.2. At least 66 personnel from 33 bone marrow transplantation centers trained on bone marrow transplantation curative protocols.

2.3. At least 56 personnel from 28 tissue typing laboratories trained on HLA Typing, molecular and serologic techniques.

- 2.4. At least 10 personnel of National Tissue Data Bank trained on finding out relation between tissue typing results in the voluntary donor centers and patients in the waiting list.
- 2.5. At least 5 personnel of National Allogenic Cord Blood Collection Center trained on quality control tests, serologic and immunologic tests and on the processing of stem cell.
- 2.6. At least 27 regional coordinators of Voluntary Donor Centers trained on the peripheric blood, taking sample from buccal swap and giving psychological support to voluntary donors.
- 2.7. At least 33 personnel from 66 Public Apheresis Centers trained on taking samples from donors, their storage and packaging
- 2.8. At least 6 personnel from MoH trained as trainers in 6 aspects.

Means: Service Contract

### Activity 3. Establishment of Data Collection System

- 3.1. Statistical information forms to be used in TÜRKÖK which are alike to other EU countries Prepared.
- 3.2. Training on how to use these forms provided.

Means: Service Contract

### Activity 4. Accreditation

- 4.1. Guidelines and forms of the international accreditation agencies such as JACIE, EFI, and EUROCORD translated.
- 4.2. Trainings that are necessary for accreditation conducted.
- 4.3. Training on standard operating procedures and checklists for regular inspections of all tissue typing laboratories, hematopoetic stem cell transplantation centers, apheresis centers, voluntary donor centers, cord blood banks conducted.

Means: Service Contract

3.5 Conditionality and sequencing: Establishment of TÜRKÖK finalized, tissue typing laboratories, hematopoetic stem cell transplantation centers, apheresis centers, voluntary donor centers, cord blood banks set up.

Sequencing:

Basic sequencing of the activities will be as follows:

Revising the degree of alignment of Turkish legislation

- Preparing draft legislation
- Identifying the trainers and training needs
- Implementing the training program
- Preparing forms for TÜRKÖK
- Preparing accreditation guidelines and providing accreditation oriented training

3.6 Linked activities: N/A

3.7 Lessons learned:

The past EU funded projects conducted by the Ministry of Health shows the fact that the mobility of the staff who take part in the project negatively effects the success of the project.

Under the light of this fact the necessary measures will be taken by the Ministry in order to avoid the above mentioned situation.



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**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)
Service Contract	X	-	3.000.000	3.000.000	2.700.000	90	300.000	10	300.000	-	-	-	-
TOTAL IB			3.000.000	3.000.000	2.700.000	90	300.000	10	300.000	-	-	-	-
TOTAL INV			-	-	-	-	-	-	-	-	-	-	-
<b>TOTAL PROJECT</b>			<b>3.000.000</b>	<b>3.000.000</b>	2.700.000		300.000		300.000	-	-	-	-

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
Service Contract	Q1 2010	Q1 2011	Q1 2013

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

## 6. Cross cutting issues (where applicable)

### 6.1 Equal Opportunity:

Equal participation of women and men will be secured through appropriate information and publicity material, in the design of projects and access to the opportunities they offer. An appropriate men/women balance will be sought on all the managing bodies and activities of the programme and its projects

### 6.2 Environment:

This project has no negative impact on environment.

### 6.3 Minorities:

According to the Turkish Constitutional System, the word minorities encompass only groups of persons defined and recognized as such on the basis of multilateral or bilateral instruments to which Turkey is a party. This project has no negative impact on minority and vulnerable groups.

**ANNEX 1: Logical framework matrix in standard format**

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number	Improving tissue and cell treatment coordination and supervision system
	Contracting period expires 2 years after the signature of the Financing Agreement	the final date for disbursement: 1 year after the end date for the execution of contracts
	Total budget : 3,000,000 €	IPA budget: 2,700,000€

Overall objective	Objectively verifiable indicators	Sources of Verification
To contribute to the efforts of Government of Turkey, towards ensuring the safety and quality of human tissues and cells from donor to patient, in line with the EU legislation.	<ul style="list-style-type: none"> <li>- The number of transplantations increased to 4000 transplants by the end of 2015</li> <li>- The ratio of non-disease and general survival increased in transplantation patients to the level of EU countries by the end of 2015</li> <li>- The first 100-day mortality in transplantation patients decreased to &lt;5% for autologue transplantations and to &lt;20% for the allogenic patients by the end of 2015</li> <li>- Problem of waiting in the patient waiting list is eliminated</li> </ul>	<ul style="list-style-type: none"> <li>· Turkish Cell Coordination Center (TÜRKÖK) statistics unit</li> <li>· Auditing reports of Ministry of Health</li> <li>· Back payment notifications of Social Security Intuition</li> <li>Records of scientific advisory boards</li> </ul>

	by the end of 2015. - At least 20 % of the support allocated as a source to the clinic and experimental research and development activities on stem cell.		
<b>Project purpose</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
To provide coordination and supervision in the field of hematopoietic stem cell transplantation treatment and studies in Turkey, raise the number of donors and ensure that the units are in coordination with the EU standards.	·The number of donors increased to 3000 per million populations ·60 % of the patients treated.	·Turkish Cell Coordination Center (TÜRKÖK) statistics unit ·Records of communication center of Ministry of Health ·Patient satisfaction surveys	
<b>Results</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
1. Legislation on tissues and cells are aligned with the EU. 2. Administrative capacity of personnel working at tissue data bank, voluntary donor centers and cord blood banks improved. 3. Data collection	1. Legislation adopted by the 1 <sup>st</sup> quarter of 2011 and implementation started. 2. Treatment rate raised from %25 to %60. bed occupation raised from %45 to %60. 3. Monthly flow of info and	·Official Journal and EU progress reports  ·Records about certificate numbers given by Ministry of Health ·Records about certificate numbers taken from abroad ·Records of International World	·To put forth an effort by private sector to integrate to the system ·To increase public awareness

system strengthened.  4. International standards attained for bone marrow centers, tissue typing laboratories, and cord blood banks.	reporting.  4. 5 bone marrow transplantation centers, 5 tissue typing laboratories and 2 cord blood bank attained accreditation.	Health Organization ·Project annual reports	
<b>Activities</b>	<b>Means</b>	<b>Costs</b>	<b>Assumptions</b>
1.1. Turkish legislation revised 1.2. Draft legislation in line with the EU acquis prepared. 1.3. Guidelines for cell collection, processing, production and banking facilities prepared.  2.1. Curricula and 6 modules for training; bone marrow, tissue typing lab, tissue data bank, allogenic cord blood collection centers, voluntary donor centers and public apheresis centers prepared and published. 2.2. min. 66 personnel from 33 bone marrow	Service Contract	€ 3.000.000	·Increase in the number of voluntary donors and formation of public awareness throughout this way.

<p>transplantation centers trained on bone marrow transplantation curative protocols.</p> <p>2.3. min. 56 personnel from 28 tissue typing laboratories trained on HLA Typing, molecular and serologic techniques.</p> <p>2.4. min. 10 personnel of National Tissue Data Bank trained on finding out relation between tissue typing results in the voluntary donor centers and patients in the waiting list.</p> <p>2.5. min. 5 personnel of National Allogenic Cord Blood Collection Center trained on quality control tests, serologic and immunologic tests and on the processing of stem cell.</p> <p>2.6. min. 27 regional coordinators of Voluntary Donor Centers trained on the peripheric blood, taking sample from buccal</p>			
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swap and giving psychological support to voluntary donors.  
2.7. min. 33 personnel from 66 Public Apheresis Centers trained on taking samples from donors, their storage and packaging  
2.8. min. 6 personnel from MoH trained as trainers in 6 aspects.

3.1. Statistical information forms to be used in TÜRKÖK which are alike to other EU countries Prepared.  
3.2. Training on how to use these forms provided.

4.1. Guidelines and forms of the international accreditation agencies such as JACIE, EFI, and EUROCORD translated.  
4.2. Trainings that are necessary for accreditation conducted.

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<p>4.3. Training on standard operating procedures and checklists for regular inspections of all tissue typing laboratories, hematopoetic stem cell transplantation centers, apheresis centers, voluntary donor centers, cord blood banks conducted.</p>			
			Preconditions
			<ul style="list-style-type: none"> <li>· Establishment of TÜRKÖK finalized, tissue typing laboratories, hematopoetic stem cell transplantation centers, apheresis centers, voluntary donor centers, cord blood banks set up.</li> </ul>