2 nd QUARTERLY REPORT

Improvement of the safety, quality and availability of organs, tissues and cells for transplantation

Member State Partner

The Ministry of Health of Italy
In cooperation with National Transplant Centre

Beneficiary Country Partner

Ministry of Health of the Slovak Republic

BC Final Recipient

University Hospital Ružinov in Bratislava (Slovak Republic)

04 July 2007

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ABBREVIATIONS

BC	Beneficiary Country (Slovakia)
CA	Contracting Authority
CFCU	Central Financing and Contracting Unit
CNT	Centro Nazionale Trapianti (Italian National Transplant Centre)
CTB	Central Tissue Bank
DPL	Deputy Project Leader
DPM	Deputy Project Manager
FRP	Final recipient of the Action (University Hospital Bratislava)
HCB	Hemopoietic Cell Bank
IEB	International Eye Bank
IT	Italian Republic
MoH	Ministry of Health
MS	Member State (Italy)
MSP	Member state partner (CNT)
PL	Project Leader
PLs	Project leaders
PM	Project Manager
RTA	Resident Twinning Advisor
RTA-A	Resident Twining Advisor - Assistant
SC	Steering Committee
SCOT	Slovak Center for Organ Transplantation
SG	Subgroup
SR	Slovak Republic
STE	Short Term Expert
TA	Technical Assistance
TS	Technical Specifications
UHB	University Hospital Bratislava

Section 1. Project data

Twinning Contract No.	200501746404-0201-0001
Project title	Improvement of the safety, quality and availability of organs, tissues and cells for transplantation
Twinning partners	Ministry of Health (IT), in cooperation with the National Transplant Centre (IT) Ministry of Health (SK), University Hospital Ružinov in Bratislava (SK)
Report	2 nd Quarterly Report
Period covered by the report	05 March 2007 – 04 June 2007
Duration of the project	24 months

Rapporteur Member State	Rapporteur Beneficiary Country
Mr. Alessandro Nanni Costa, project leader	Mr. Richard Rasi, project leader

Section 2. Content

2A – Background

Policy Developments

1. 1. Beneficiary Country policy developments in the sector

The Ministry of Health of Slovak Republic (MoH SR), as a central state administration body in the health sector, is responsible for implementation of Directive 23/2004/EC in general and it has appointed, by its decision, tissue establishments to be responsible for direct implementation and execution of that Directive in the praxis.
In the area of tissue, cells and organ procurement and transplantation there are two main types of organizations: 1) tissue establishments and 2) organ transplantation centres.

1. 2. Beneficiary institutions and other parties involved

The first tissue establishment in the Slovak Republic was linked to Ružinov General Hospital in Bratislava and started its activity in 1988. The list of currently existing tissue establishments under the competence of the SR Ministry of Health is as follows:

1. Central Tissue Bank, University Hospital Ružinov, Bratislava, multi-tissue bank
2. Associated Tissue Bank, University Hospital and Medical School, Košice, multi-tissue bank
3. International Eye Bank, Petržalka University Hospital, Bratislava , eye bank
4. International Eye Bank, F.D.Roosewelt Hospital, Banská Bystrica, eye bank
5. Hemopoietic Cell Banks (HPC banks) - 3 in Bratislava, 1 in Banská Bystrica, 1 in Martin, 1 in Košice, 1 in Prešov

In addition, there are non-governmental and private organisations such as:

6. Slovak Register of Cord Haemopoetic Cells (EUROCORD), Bratislava, cord blood bank
7. Private Hospital Košice - Šaca Tissue Bank

As regards organ transplantation centers, all of them are under the responsibility of the MoH as follows:

- Slovak Centre for Organ Transplantation – Slovak Medical University (SCOT) with 5 Regional Transplantation centres
    1. Transplant centre University Derer's hospital, Bratislava (kidneys, liver)
    2. Transplant centre, Slovak institute for heart diseases, Bratislava, (heart)
    3. Transplant centre University hospital, Martin (kidneys)
    4. Transplant centre Roosevelt hospital, Banská Bystrica (kidneys, pancreas)
    5. Transplant centre, University hospital, Košice, (kidneys)

The public awareness towards organ, tissues and cells donation is very low in Slovakia. The main reason for this is a lack of public awareness and a lack of financial resources. The result

is a very low rate of donations, which achieves annually less then 10.2 donations in 2004 per 1 million of inhabitants in organ transplantation.

A reason why problems such as a lack of donors and long waiting lists for organ donations occur is the presently unsatisfactory information system that is not unified, and interconnected, neither between the tissue establishments, nor with the Central donor and non-donors register located at the SCOT in Bratislava. This means that for example information about a possible donor in one tissue establishment is not at disposal in the whole network. Secondly, the information system for organ transplantation does not include the requirements of tissue and cell establishments and it is not compatible with the requirements of the Directive 23/2004 EC. A central information system managing waiting and donor lists for organ donations is already 10 years old and needs to be upgraded. The required data confidentiality, data protection, and data storage time cannot be as yet fully assured.

Additionally, each tissue establishment elaborated its own quality management system, which mostly does not conform to contemporary regulatory and quality requirements of the European Communities. These systems strongly need to be unified as well as updated according to the latest EC Directive 23/2004/EC.

Regarding the institutional framework of the quality control, it is monitored by national authorities: Slovak National Accreditation System (SNAS) and State Institute for Drug Control (SIDC). SNAS controls the good laboratory praxis, and SIDC is responsible for good manufacturing praxis.
Establishments have to fulfil the accreditation criteria as ruled by the above-mentioned authorities. The project will give a framework for compatibility of national and EC requirements for safety and quality management in field of organ, tissue and cell transplantation.

Project assumptions

The assumptions as formulated in article 3 of the Work plan are

- Current legislation in force
- Trained staff will stay on their positions, using the acquired knowledge
- Institutions involved in the unified info system cooperate and actively use the system
- Willingness of particular institutions to participate and provide data
- Relevant staff available for planned training
- Technical facilities available for the training

The above mentioned assumptions imply that, using the current legislation in force, in particular the ones entered into force on 2006 and at the beginning of 2007, the institutions and all involved staff will actively participate at the project taking advantage of the planned training, using their acquired knowledge, providing data and actively using the unified info system. Staff and hospital facilities will be fully available for planned training.

Project objectives

- **General**: Ensure a high standard of quality and safety for donation, processing and distribution of human tissues and cells in the Slovak Republic to achieve a satisfactory implementation of the European Community Directive 2004/23/EC.
- **Specific**: Introducing quality management for organ transplantation, tissue and cell banking, to assure the highest possible level of public health protection.

Benchmarks

- The facilities included in the project accredited by the beginning of 2009, fulfilling the requirement of the directive 2004/23/EC. Following some delays in the finalization of the Twinning Contract and the start up of the project on 4th December 2006 with its conclusion on November 2008, it has become necessary to postpone the date of accreditation of the facilities, which originally was foreseen by the end of 2007.
- Increasing the number of successful transplants
- Increasing the number of real donors from indicated donors by 10%.
- Decreasing the insufficient number of donors by 5%.
- 100 employees of tissue and cells establishments and organ transplant centres trained on QMSG
- tissue and cells establishments and organ transplant centres using new developed system by the end of the project (in the contract originally foreseen by the end of 2007)

Achievements of mandatory results

Audit report produced and corrective and preventive actions plans in place / Component I

- QMS for tissue and cells establishment and transplantation centres developed and introduced:
  Quality management system guide (QMSG) developed
  Tissue establishment and transplant centre staff trained / Component II
- Unified information system for transplantation centres, tissues and cell establishments (developed and implemented within TA contract) and tested / Component III

- Proper public dissemination of the project outcomes/Guidance brochure / Component IV

The following **Mandatory Results** were completed:

Component 1:

- Audit report produced and containing audit conclusions suggesting corrective and preventive actions

Activities in the reported period

Here below is a table summarising the STE missions.

Activities	Name of expert	Dates of mission	Topic	Total days in the work plan	Days worked	Completed %
Component 1	**Elaboration of an audit analysis of the current situation in the field**					
	Project Co-ordination/Management			**8**	**1**	
	NANNI COSTA Alessandro	22-23/03/2007	1st Quarterly Committee	8	1	
Activity 1.4	**Reports and networking activities**			**9**	**3**	**33%**
	BARIANI Fiorenza	22-23/03/2007	Audit Reports Conference	3	1	
	PICCOLO Giuseppe	23/03/2007	Audit Reports Conference	3	1	
	FEHILY Deidre	22-23/03/2007	Audit Reports Conference	3	1	
Activity 2.1	**Elaboration of Quality Management System Guide**			**15**	**13,5**	**90 %**
	PICCOLO Giuseppe	13-15/05/2007	QMSG	5	2	
	MIGLIACCIO Giovanni	13-14/05/2007	QMSG	2,5	1	

	FEHILY Deirdre	13-15/05/2007	QMSG	5	2	
	BARIANI Fiorenza	14-15/05/2007	QMSG	2,5	1	
	MIGLIACCIO Giovanni	27-28/05/2007	QMSG		1	
	PICCOLO Giuseppe	28-30/05/2007	QMSG		2,5	
	FEHILY Deirdre	28-30/05/2007	QMSG		2,5	
	BARIANI Fiorenza	28-30/05/2007	QMSG		1,5	
Activity 2.2	**Provision of set of specialized trainings**			**106**	**9**	**8,49 %**
	PERITORE Daniela	15-16/05/2007	Site visit for training		1	
	RIDOLFI Lorenza	15-17/05/2007	Site visit for training		2	
	GHIRARDINI Angelo	15-17/05/2007	Site visit for training		2	
	GHIRARDINI Angelo	27-29/05/2007	Site visit for training		2	
	RIDOLFI Lorenza	27-29/05/2007	Site visit for training		2	
Activity 3.1	**Preparation of the unified information system**			**13**	**2**	**15,38 %**
	GHIRARDINI Angelo	26-28/03/2007	Information system		2	

Activity of Component I: 1.4 Reports and Network Activity

The Audit Report Conference

On March 23 , 2007 it was held in Bratislava at MoH the Audit Report Conference, with the participation of coordinators of Italian STExperts and the representatives of audited transplantation centres .
Mr Kuba (SCOT) was the moderator of the Conference: Mr Piccolo presented the audit results about organ transplantation centres, Ms Fehily those related to tissue and eye banks and Ms Bariani (as a substitution of Mr Migliaccio) the reports from HPCBanks.
At the end of slide presentation, Mr Nanni Costa was available (together with the STExperts) to answer to all questions raised from the audience and a rounde table was held.
It was mainly clarified again the goal of the Audits, performed in order to obtain a clear picture of the situation and consequently to produce an appropriate QMSGuide for the transplantation system in Slovakia, fostering the EU Directives for tissue and cells and EU suggestions for organs.
In fact on the same day it was held a workshop between italian STE and slovak PM Mr Koller and DPM Mr Kuba (with the presence of Italian PL Mr Nanni Costa and SPO Ms Pikulova), in order to plan the following activity represented by the development of a QMSGuide: it was decided to perform this activity on May 2007, according to the time schedule.
In the "Assessment" and "Issue arisen" sections of this report there will be some comments on this activity 1.4 , fully integrated and in continuity with the comments related to activities of Component II and Component III.

Activities of Component II : Design and implementation of unified management system

All the Activities will be described in this section and commented in the Assessment section.

- Elaboration of Quality management System Guide (QMSGuide)
- Provision of set of specialized trainings (short term courses and medium term courses for tissues and organs)

- **2.1 Elaboration of QMSGuide:**

During May 2007 the Twinning team (Mr. Lauro and Ms. Kotzigova), together with PM Mr. Koller, DPM Mr. Kuba, the Slovak HPC expert Mr. Mistrik and tissue expert Ms Jarabinska, met at Ruzinov hospital with italian STEs Mr Piccolo (organs), Ms Fehily (tissue), Mr Migliaccio (cells) and Ms Bariani (cells) in order to develop the QMSGuide for Slovak Republic. Mr Rosocha (tissue expert from Kosice) participated at the development of the guide as well, even if it was not possible for him to be present at the Ruzinov hospital meetings, held during half and end of May 2007.The main aim of this activity was to apply the above mentioned EU Directives on tissue and cells to the transplantation system of Slovakia, adding some suggestions on organ transplantation. The Quality Management System Guide was developed with the aim of improving overall quality management in tissue, cell and organ establishments. It is divided into two main parts: a general and a specific one.

The general part covers the following points:
- general principles of good clinical and laboratory practices.
- general guidelines for QMS (Quality Management System) and will be unified for both tissues and organs.

The specific part covers:

-guidance for writing the standard operating procedures
-training and reference manuals for staff
-reporting forms
-donor records and follow up forms for the transplanted organs, tissues and cells, separately for tissue and cells and for organs.

The Guide will be produced in Slovak and English

The deadline for producing the English and Slovak version of QMSGuide is July 31st 2007 and it will be completed in adherence with time schedule of the twinning project.

A major objective of the project is the design and implementation of the Quality Management System Guide which aims to provide tools which will help to raise the quality of the whole transplantation process of organs, tissues and cells in Slovakia.

This guide has been developed by technical experts from the fields of organs, tissues and cells in Italy and Slovakia. The platform for the definition of quality and safety standards was provided by three European Union Directives; 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 and its two associated technical directives, Directive 2006/17/EC and Directive 2006/86/EC. A number of Italian, Slovak and international documents have been consulted in the course of its development, notably the Council of Europe Guide to Safety and Quality Assurance for Organs, Tissues and Cells (3rd Edition). The guidance provided here is consistent with current transplant legislation in Slovakia.

The scope of this guide extends to quality assurance standards for procurement, preservation, processing and distribution for organs, tissues and cells of human origin (allogeneic and autologous) used for transplantation purposes. Blood, blood products and somatic and genetic

cell therapy products and tissue engineered products are excluded from the scope of these guidelines. Genetically modified human materials are considered to be medicinal products (EU Directive 2004/27/EC) and additional requirements apply which are not included in this Guide.

The definitive version of the guide will be annexed to 3rd quarterly report.

■ 2.2 Provision of set of specialized trainings (short term courses and medium term courses for tissues and organs)

2.2.1 Designing **SHORT TERM COURSES**:

These courses were foreseen in the twinning contract with the aim to cover general aspects of organ and tissue donation and procurement such as:
-transplant procurement management,
-donor detection, identification and clinical evaluation,
-brain death diagnosis,
-non heart beating donors,
-clinical examination simulation,
-donor maintenance,
-family approach for organ and tissue donation,
-application of selection criteria,
-review of clinical cases,
-retrieval organization,
-organ procurement,
-tissue procurement, packaging and labelling,
-allocation system,
-ethics and legislation.

REVIEWING TOPIC OF THE SHORT TERM COURSES: following a meeting in Bratislava at the end of March between the RTA Mr Lauro, the DPM Mr Kuba and the Information Network System STE Mr Ghirardini, it was reported by Mr Kuba that the level of expertise of transplant coordinators and anesthesiologists (responsible for donation and procurement of organs and tissues in Slovakia) is nowadays higher than expected in the original version of the twinning contract.
Two useful suggestions were made to RTA by Mr Kuba and Mr Ghirardini separately, in order to develop a short term course more advanced than foreseen in the contract and consequently more useful and updated: Mr Kuba suggested the participation of the Italian PL Mr Nanni Costa with RTA at the local ETCO (European Transplant Coordinators Organization) course, held in Jahodna-Kosice at the end of April 07, in order to understand clearly the level of knowledge and expertise of transplant coordinators and local anesthesiologists. Mr Ghirardini suggested to add - as an additional action to the twinning contract - some site visits on Slovak coordination centres located in Bratislava, Martin, Banska Bystrica and Kosice, made by an Italian STE, in order to verify the activity in the centres, to assess their training needs and to discuss directly with local coordinators how to develop a useful short term course. It was added a visit to Slovak Centre for Organ Transplantation (SCOT) in Bratislava for the same purpose and the aim to better understand

the network between SCOT and coordination centres located in Bratislava, Martin, Banska Bystrica and Kosice.
Both the suggestions were discussed by RTA with Italian PL and were fully approved by Mr Nanni Costa.
Mr Nanni Costa appointed Ms Ridolfi as a new STE in order to visit all Slovak coordination centres, as well as he appointed Ms Peritore in order to visit SCOT. He either delegated Mr Lauro (RTA) to attend the local ETCO course in Kosice. Because of the change of the Slovak SPO during April 2007, the RTA had the possibility to discuss these topics with the new SPO Mr Skorvaga only on May 2007, but he kept informed Ms Krbatova (previous Slovak SPO Assistant) about all these new activities. The Slovak PL approved all these site visits to coordination centres and SCOT as well as the new Italian STE Ms Ridolfi and Ms Peritore.

-**JAHODNA (KOSICE) ETCO MEETING participation by RTA on April 2007**: the RTA attended the course and had the possibility to present the twinning project to all transplant coordinators and some anesthesiologists of Slovakia. The course was useful to the twinning project as it was possible for the RTA to discuss with local coordinators the way how to develop the short term course. The impression was that a possible course aimed to marginal donors and tissue procurement could be as advanced as it is required by the level of knowledge and expertise of the coordinators and anesthesiologists. It is worthwhile to notice that these remarks, made by RTA, are the same as those independently reported by Mr Piccolo (organ STE) and Ms Fehily (tissue STE) during their audit in the transplantation centres during February 2007. It was also noted by RTA that almost all the topics, foreseen inside the draft of the short term course in the twinning contract, were fully debated and taught during this local ETCO course.

-1 DAY SITE VISIT AT SCOT-Bratislava by Ms Peritore on May 2007: The one day visit at SCOT, performed by STE Ms Peritore, was especially useful in order to understand better the role of SCOT inside the coordination network in Slovakia and to make some suggestions to empower SCOT as a central point inside the coordination net. Ms Peritore had the possibility to talk to Mr. Kuba, the head of SCOT, and was able to visit all the facilities. Actually, SCOT doesn't play an essential role in full control of the process of organ donation, in the evaluation of the donor and organ suitability, in the verification of a correct utilization of all available organs, neither it is consulted to give a professional or scientific support to solve prospective problems.
Ms Peritore suggested, that the SCOT should promote scheduled meeting with the regional coordinating units in order to create a "community" where to exchange know-how, to share common scientific protocols, to discuss approaches, to improve the utilization of the marginal organs and to standardize the allocation procedure in the regions.
It is worthwhile to notice, even in this case, that Ms Peritore came up to the same conclusion made by Italian PL Mr Nanni Costa during the Audit Report Conference, held in March 2007: there is a lack of sense of "transplant community " in Slovakia and a real need to create a proper network between centres. It is not by chance that the same conclusion was made by STE Ms Ridolfi after her tour of 4 Slovak coordination centres, as it is reported later. At conclusion of Ms Peritore's SCOT visit, she reinforced the idea of creating a network enabling the fast communication of anamnestic, clinical and instrumental data relative to the potential donor: this could be the other topic of the Short Term Courses – the development of

a Network between Coordination Centres and SCOT, and the same conclusion was confirmed later by STE during their tour among 4 coordination centres.

The report of Ms Peritore's 1 day side visit is added as Annex 1.

– 1 DAY SITE VISIT IN 4 COORDINATION CENTRES in Bratislava, Martin, Banska Bystrica and Kosice by STE Ms Ridolfi, together with STE Mr Ghirardini:

During the month of May 2007 the Italian STE Ms Ridolfi, together with STE Mr Ghirardini, visited the 4 coordination centres located in Slovakia.

In Bratislava they met local coordinator Mr Vateha, in Martin Mr Miklusica, in Kosice Mr Bena and in Banska Bystrica Mr Sykora. In every coordination centre they spent a day, discussing the activity inside every single institution and talking about the short term course.

At the end of the tour the RTA had a meeting with Ms Ridolfi, in order to have an immediate feedback of the tour, even earlier of her official report. The STE Ms Ridolfi and Mr Ghirardini came to the conclusion that there is a need to improve the network between coordination centres, to review the role of SCOT as well as the criteria of "marginal donors".

In order to organize the short term courses, Ms Ridolfi made the purpose of an "interactive way" of teaching (besides a conventional course), with Italian and Slovak "teachers" together performing "role playing" meetings inside small groups of trainees and discussing how to organize better the network of donations and transplantations in Slovakia.

The report of Ms Ridolfi and Mr Ghirardini 1 day site visit is added as Annex 2 .

- RE-DESIGNING TOPIC OF THE SHORT TERM COURSES: Following all these activities, a decision was made by RTA and Italian STEs in order to change the topic of short term courses. RTA discussed it at the May monthly meeting with new SPO, Mr Skorvaga and CFCU Mr Skvarka. Italian CNT fully approved the change.

The draft of the 2-days short term course should foresee a first day dedicated to an "interactive course", with Slovak coordinators and anesthesiologists interacting with Italian STE in order to actively discuss the way of improving the network between coordination centres and designing a common "organizative model "of a coordination centre. A second day should be more conventionally dedicated by STE to the two main topics like the use of marginal donors and the tissue procurement. Because of the re-designing of the course and the fact that there was a local ETCO course held recently in Slovakia, the plan is to postpone this course after the deadline (August 31st , 2007), into the autumn time.

Making a summary, the Short Term courses will be developed and updated to the level of expertise of slovak coordinators and anesthesiologists, taking care of the procurement and donation process. STE will add,to the already designed topics of these courses, 4 main lectures on tissue procurement, marginal donors, common organizative model of coordination centre and improving network between SCOT and centres.

MEDIUM TERM COURSES:

Generally MEDIUM TERM COURSES are dedicated to transplant centre trainees in order to teach them how to apply and use on a daily working basis the QMSGuide.

2.2.2 Designing **MEDIUM TERM COURSES** addressed to tissue establishments:

Such courses will be delivered as contribution of STEs to the already designed 1-year training for tissue bank personnel that was performed in SR. Particular contents were agreed by IT and SK in-the-field experts upon discussion of the syllabus of this course in the period of QMSG development. The main change, decided by Slovak and Italian experts during the development of QMSGuide, was to add the **HPC bank trainees** to the course, as the QMSGuide is dedicated to cell transplantation as well. This suggestion was made by Italian and Slovak experts, together with coordinator of tissue medium term courses Ms Fehily, DPM Mr Kuba and PM Mr Koller and it was presented and fully discussed at the last May monthly meeting with the SPO Mr Skorvaga and CFCU Mr Skvarka.

2.2.3 Designing **MEDIUM TERM COURSES** addressed to organ transplantation centers:

The course will focus on the application of quality management principles derived from the quality system management guide as far as organ transplantation centers are concerned.
In this case the experts will make some suggestions, because there is still no precise EU directives on QMSGuide for organs.

These specific trainings provide an explanation of the specific parts of the QMSG according to each group's specialization. Trainings will be provided for about 50 health care personnel and 50 staff of tissue and cells establishments and organ transplantation centers.
Both Short and Medium term courses will need support from simultaneous translation, foreseen inside the twinning contract.
During last monthly meeting held in May, an extra support for the medium term courses was asked by RTA to MoH (Mr Skorvaga), as inside the TW Project a financial support for travel and accomodation expenses of the Slovak trainees is not foreseen. RTA is awaiting the decision of MoH. Medium term courses were foreseen by the TW contract to be held during July and August 2007. A decision was made by Slovak and Italian experts to postpone them on September 2007 (the foreseen deadline was August 31st 2007), in order to obtain the maximum attendance of Slovak trainees. This decision was communicated by RTA to MoH (Mr Skorvaga) during last monthly meeting as well.

Activities of Component III: Development of a specific software

All the Activities will be described in this section and commented in the Assessment section.

3.1 Preparation of the Unified Information System

The unified information system is being developed in parallel to activities of component 2. In general terms it has to respond to the requirements set up by the Directive 23/2004/EC and it has to be compatible with similar information systems used in other EC countries.
The activities are carried out by Italian STE Mr Ghirardini supported by additional Italian IT specialist Ms Scaglia, recently appointed in the TW project. Both STEs are preparing complete software specification (terms of reference) for a unified information system for transplantation centers, tissue and cell establishments. They are cooperating with SK Working group, represented especially by DPM Mr Kuba, who is responsible for old central software at SCOT. IT STEs also are preparing the system of assessment and evaluation criteria that will be applied when evaluation of the service is performed. The recommendations of how to control particular phases of the software (SW) development process are being prepared as well. Some data structures will be provided to Mr Kuba by STE during the development of software.

These experts will define the conditions, outputs and inputs and functionality of the special software, data model, and structure, hierarchy and user rights in the information system. Special attention will be given to data and network safety, encryption of personal data and means/channels to transfer historic data from previous system to new developed software. The system will cover the following characteristics:

- Establishment of a web-based information network that will allow submission and reading of data for all participating organizations with defined specific access rules
- Establishment of a central registry serving for all the Slovak tissue establishments and transplantation centers
- Establishment of a system for identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8 of the Directive 23/2004/EC.
- Introduction of a single European coding system to provide information on the main characteristics and properties of tissues and cells implemented into Slovak tissue and cell establishments, following the Technical Requirements to the Directive 23/2004/EC
- Compatibility with the bar coding system which is planned to be introduced for tissue and cell establishments by the EC, and shall be specified in the Technical Requirements
- Access to relevant parts of the registries of the SCOT
- Introduction of comprehensive record keeping of all the tissue and cell establishments
- Acting as an information exchange system between the tissue and cell establishments in the Slovak Republic regarding availability of tissue and cell grafts, adverse events and serious adverse events reporting
- Acting as information exchange between donor detection organizations and tissue and cell establishments

The SW specification will also include detailed description of requirements on the experts and IT company that will develop the unified software.
Two missions were held, at the end of March 2007 by Mr Ghirardini and in the middle of June 2007 by Ms Scaglia together with Mr Ghirardini: both the missions were directed to make STEs familiar to SCOT national old unified information system (Mr Ghirardini's first mission) and software (Ms Scaglia and Mr Ghirardini's mission) .
During both missions Mr Kuba explained to STEs the computerized old network between SCOT and transplant centres, underlining the need to update the software. Two further main topics were discussed : the tender for Slovak IT company and the need for hardware.

– IT COMPANY and TENDER:
  The requirements for the tender are under development by a strict collaboration between Slovak and Italian experts and it is foreseen that the tender will take place between summer and autumn time, in order to have the Slovak IT company ready to start to work on the development of the new software by December 2007 (deadline for this issue).

- HARDWARE (HW):
Mr Ghirardini stated that SW to be developed in the project will require a complementary HW (server) to be fully operational and to secure sustainability at the same time.
Therefore it is necessary to add additional finances from the Ministry of Finance (for the Ministry of Health) to provide the HW: more financial support will be needed in the next following years for the maintenance and upgrading of the software as well.
All STEs agreed on this point.
This topic was discussed by RTA with SPO Mr Skorvaga and CFCU Mr Svarka during last monthly meeting in May.
Information about the request to modify the Project Fiche (paralel co-financing for the SW): the request was approved by PAO, NAO and NAC and notified to DG Enlargement in Brussels on 20.06.2007, since then there is 10 days time for EC to object to this modification.
This topic is added as Annex 4.

No delays were foreseen for this activity 3.1 and the deadline of July 31st 2007 is fully respected in advance.

The second **Steering Committee** was held on June 27th 2007. The participants were: RTA Mr. Lauro, RTA-A Ms Kotzigová, Deputy PM Mr Kuba, SPO Mr Skorvaga, Ms Vallova (MoH),CFCU Mr Škvarka,, Formez representatives Ms Scordino and Mr D'Angelo.
PM Mr Koller and Italian PL Mr Nanni Costa couldn't attend and delegated respectively DPM Mr Kuba and DPL Ms Agger. Mr Rasi (SK PL),Mr Hochel and Mr Kluka (MoH) were invited as well as Ms Gabcova from Governamental office.The progress of the project during last 3 months (April-May and June 2007) was discussed, together with the 2nd quarterly report.

Mr Rasi , Mr Hochel, Ms Gabcova and Ms Agger couldn't attend the meeting for professional and/or personal reasons.

Timing & Delays

Adherence to schedule

In the second quarter, there have been implemented the activities of Component 2 and 3 according to the schedule of the twinning work-plan with a minor change in activity 2.2 as reported below:

Project Month		5	6	7	8	9	10	11	12		
Component 2. Design and implementation of an unified management system											
2.1 elaboration of QMSG											
2.2 provision of set of specialized trainings **2.2.1 short term courses** **2.2.2 medium t.c. tissue** **2.2.3 m.t.c. for organ tr.**											
Component 3. Development of a specific software											
3.1 preparation of the unified information system											

Expected to be delayed

Recuperation of delays

Component 2.1 (Elaboration of QMSGuide) will be completed on time, in adherence with its deadline on July 31st 2007. Component 2.2 (Short and Medium Term Courses) will be delayed due to re-designing of short term courses and due to need to implement the attendance to medium term courses (originally foreseen during July and August 07):both the activities will be postponed after Summer 07. No delays are expected for Component 3: activity 3.1 (Preparation of Unified Information System) will be running in adherence with time schedule and activity 3.2 (public procurement for Slovak IT company plus beginning of activity of Slovak IT company) is foreseen in adherence with the time schedule.

Assessment

Overall assessment of progress

The Audits performed by Italian STEs during Component I, among organ, tissue and cell establishments in Slovakia, were necessary in order to get a clear picture of the 2007 current in-the-field situation of transplantation in Slovakia. The idea to use these Audits for

"accreditation" of the slovak transplant centers was discussed by RTA and SPO during last monthly meeting (and it will be extensively overviewed in the "Issue arisen " part of this report). RTA and SPO came to the conclusion that this topic is marginal to the real reason of the Audits, and it is not mandatory for MoH to use these Audits for the accreditation. Indeed, the Audits were the first necessary step in order to develop and write an appropriate QMSGuide, updated and adherent to the real transplant situation of Slovakia: therefore the application of EU Directives (main aim of the QMSGuide) is performed with adherence to the Slovak transplant reality in 2007. The accreditation process should go through approved goverment authorities and is based on national laws, which are different from audit performed by italian experts.

Under this point of view, the participation of Slovak experts in organ, tissue and cell field was implemented in order to have even a better picture of the legal framework and the real need of the transplant centres. On the other hand, the QMSGuide was really necessary in order to update and substitute the quality system guides owned by single transplant centers, and to make EU Directives fully satisfied by transplant centers. Furthermore, every Guide needs to be read and applied on the field: this was the reason to have short and medium term courses inside the twinning project, in order to foster the conformity with the EU Directives reported inside the QMSGuide for Slovakia. The short term courses were originally foreseen as basic courses on donation and procurement. Because of the facts explained extensively in activity 2.2, the Audits inside transplant centres first and then the 1 day site visits to coordination centres later on, arose the need to improve the quality of this course. This has consequently changed the topic to more specific issues like marginal donors, tissue procurement, network between coordination centres and SCOT or an organizative common model of coordination centres. Medium term courses were originally foreseen as "QMSGuide application on the field" courses and they were left in this way, just adding the HPCBanks because of their extensive use of own quality system guides, not always updated and adherent to EU Directives.
It is worthwhile to notice that the Audits (and the 1 day side visits as well) were very useful in order to confirm the need to implement a real network between coordination centres, SCOT and transplant centres and to have a real updated tool in order to obtain this goal, like a specific software. The actual software is old and the net interconnections need to be improved and implemented: to improve the network between centres, it is necessary to update and improve the tool used for communication. It was necessary to perform the two missions carried out by STEs in strict collaboration with Mr Kuba. In this way, STEs could get a clear picture of the real situation of the software and of the unified information system that is nowadays being used in Slovakia among transplant centres, in order to write the appropriate requirements of public tender for the Slovak IT company. The need to implement a new hardware was added as well, in order to support better the development of the software.

Activities and goals : ***Component II and I. part of Component III***

The main goal of activity 2.1 is fully achieved: the elaboration of a QMSGuide, updated to EU Directives and adherent of 2007 real situation among transplant centres in Slovakia, was performed under the care of Italian and Slovak experts, working together in Ruzinov hospital

facilities as it was foreseen in the project. The guide was developed in English and it will be translated into Slovak by 31st July 2007.
Activity 2.2 (short and medium term courses) and its goals was better defined during the development of the twinning project, and it will be completed between September and November 2007 due to re-designing of short term courses and the need to implement the Slovak trainees attendance to the medium term courses.
Activity 3.1 and its goal was achieved as well: the new unified information system was prepared and developed inside the requirements of the public tender, in order to have the new Slovak IT company fully working by December 2007 with the support of STEs.

Following activities : *II. part of Component III and Component IV*

The second phase of Component III (activity 3.2:public tender and starting activity for Slovak IT company) will be developed by the deadline of December 2007, in close collaboration between Italian STEs Mr Ghirardini and Ms Scaglia and Mr Kuba, responsible for the software at SCOT Bratislava. The tender will be ready by the end of Summer 2007 and the starting activity of IT company will be carried out no later than end of the year (as foreseen in the project).
Finally the pilot testing (activity 3.3) for the new software will be performed between August and November 2008.
Component IV will be developed between September and November 2007, with the only exception of activity 4.3 (Closing Conference), that will be held on November 2008.
Activity 4.1 will consist of preparation of a brochure as a tool of better coordination and management of organs, tissues and cells donations, and will be used by medical professionals and transplant coordinators. The brochure will have a general part explaining the Directive 2004/23/EC. A part of the brochure will report the relevant Slovak legislation and another part will be focused on removal of the critical aspect identified in the audit activity and its general conclusions. The final part will regard the aspects related to the detection and handling of potential donors.
The brochure will be a synthetic version on paper of the guidelines (QMSGuide), which will be produced in the form of a CD (500 copies).
The brochure will be prepared by the STEs and 5000 copies will be printed within the project budget. The languages for brochures and guidelines are Slovak and English.
The reason why Activity 4.2 is foreseen is the fact that the project strives to improve the interaction and communication between the health care institutions and social community especially in regard to organ donation and transplantation.
The material will be prepared taking into consideration that a possible subsequent public awareness campaign will be launched by the Slovak competent authorities.
There will be a provision of effective information on how to assure the Slovak community of:

- the procedures used from the ethical and health authority point of view for organ transplants
- the important life saving results of those interventions
- the results obtained in other European countries.

Information material will cover organization of centers, coordination, control and evaluation programs, features that ensure transparency and quality of the Service as well as the main activities carried out by the National Transplant Center. Particular attention will also be devoted to organ donation, taking into account Slovak legislation in this specific field. The information leaflet and CD Rom or DVD materials for the general public will be prepared.

Issues arisen

- *Elaboration of QMSGuide*

The main issue arisen during this activity was the need of a close cooperation in developing the Guide between Italian and Slovak experts in organ, tissue and cell transplantation. From the Italian STEs, there were present Mr Piccolo for organs, Ms Fehily for tissues and Mr Migliaccio and Ms Bariani for cells. From Slovak STEs Mr Kuba was attending for organ transplantation, Mr Koller and Ms Jarabinska for tissue (with Mr Rosocha's support from Kosice) and Mr Mistrik for cells. As it was not possible to involve all the Slovak experts in the field, the choice to add Ms Jarabinska, Mr Rosocha and Mr Mistrik was due to the fact that Ms Jarabisnka and Mr Rosocha are responsible for the two main tissue banks along the country, while Mr Mistrik is a national recognized and well appreciated expert on HPCBanks, responsible for the HBCBank Petrzalka in Bratislava.

- *Short and Medium term courses*

The need to change the topic and timetable of Short term courses has already been discussed. The procedure applied, in order to achieve a more useful and updated course, was discussed as well.
It is worthwhile to notice that, even in this case, the main issue arisen was the real need of close cooperation between STEs and Slovak transplant community, during audits and 1 day side visits.
Concerning the Medium term courses, the only issues arisen were the need to add the HPCBanks inside the courses (to update their own old quality system guides) and the necessity to postpone the courses after the previously foreseen summer time, in order to obtain full attendance by Slovak trainees. The need to financially support these Slovak trainees (up to 100 - as it is foreseen in the project) was debated : the possibility to support accomodation and trip expenses by MoH will increase the number of slovak trainees attending the course, and this issue needs to be fully considered.

- *Unified information system and development of software (and hardware)*

It was stated that software developed in the project will require a complementary hardware (server) to be fully operational and to secure sustainability at the same time.
Therefore there is a necessity to add additional finances from the Ministry of Finance (for the Ministry of Health) to provide the hardware: more financial support for the maintenance and upgrading of the software will be needed in the following years. This issue was arisen during

activity 3.1 and it needs to be fully considered in order to have a real operative computerized network.

- *Relationships between transplant centres and MoH: the idea of a "transplant community"*

During the Audit Report Conference, held last March in Bratislava, the idea to implement the Slovak transplant community was arisen by Italian PL, Mr Nanni Costa, and fully confirmed by audit reports and, later, by 1 day site visits.
Mr Nanni Costa suggested that the best way to improve the relationship between transplant centres themselves and with MoH is to act all together as a whole transplant community, fully interconnected and tied up by clinical and scientific relationships. Mr Nanni Costa stated, that in his opinion the need of financial support of transplant centres by MoH is only a part of the problem and it cannot be the solution itself. Another option should be to empower SCOT, as suggested by Italian PL and confirmed by STE Ms Peritore, creating a different institution acting as a National Transplant Centre. This National Transplant Centre could support and manage the whole process of organ donation in cooperation with the regional coordinating units ,having a better knowledge of local factors. It could either implement operational policies covering all aspects of the donation/transplant process and at the same time guarantee the fairness, transparency and safety of the whole system. Therefore this Central Institution should guarantee the well-knowledge of the problems related to donation and transplantation, showing ability in problem solving and also controlling the entire process.

- *Meetings with selected public bodies (scientific societies) convened by the RTA and his RTA Counterpart*

This activity is foreseen by twinning team as an essential part in order to increase the awareness along Slovakia towards the development and goal of the TW project, and it can be foreseen as a part of the next activity 4.2.
In strict collaboration with PM Mr Koller and DPM Mr Kuba, the twinning team planned meetings with some scientific societies where twinning team was invited to present the project.
-National Conference of HPCBanks: RTA-A Ms Kotzigova and PM Mr Koller presented the project at the national conference of HPC banks "Meeting of transplant teams" held in Hospital of St. Cyril and Metod in Petrzalka , Bratislava on 02.02.07.
-National Conference on Kidney Transplantation: it was held in Martin on 30.03.07 and RTA and RTA-A attended the meeting to present and discuss the project.
-National Conference of Coordinators: RTA presented project developments on 18.04.07 in Jahodna-Kosice.
-NUSCH Bratislava: on 21.06.07 RTA and RTA-A presented and discussed the twinning project at the Heart Transplantation Centre (NUSCH) in Bratislava.
All these meetings represented a good opportunity to explain better the steps of the project, to answer any issues arisen by the different kind of audience and to keep in touch with the

transplant community, in order to give the audience the feeling of being fully involved in the twinning project.

- *Liver Transplantation: the "extra twinning activity"*

The following part of the text (liver transplantation: the extra-twinning activity) is mentioned only with an informative aim because it is not foreseen inside the twinning contact and it is clearly an extra twinning activity. Action should be taken in order to improve the situation of cirrhotic patients in Slovakia. At the moment the mortality rate for cirrhosis in Slovakia is the triple compared to the EU (Bratisl Lek Listy 2005), there is no active liver transplant programme and cirrhotic patients are sent abroad (Czech Republic, Austria, Germany, France) in order to be transplanted.
In 1988, Italy had the same mortality rate from cirrhosis as is nowadays present in Slovakia, e.g. approximately 3% of total mortality (Bratisl Lek Listy 2002).
Last January 2007 a meeting was held at the MoH with PL IT Mr Nanni Costa, Mr Hochel – director of the Health Sector at MoH , RTA, RTA-A, Mr Kluka (MoH SR), PM Mr Koller, DPM Mr Kuba, Mr Laca and Ms Grandtnerová (Martin Kidney Transplantation centre- Mr Laca is national expert on liver transplantation), Mr Roland (Košice Kidney Transplantation centre - head of Slovak Transplant Society). The meeting was held in order to discuss the topic of liver transplantation in SR and to try to foresee a possible solution. At the moment there is no active liver transplant centre in Slovakia and the previous transplant activity was stopped because of high mortality rate of transplanted cirrhotic patients. IT PL proposed the possibility, for liver transplantation medical and nursing staff working in Slovakia, to get a proper training in Liver Transplantation and related activities abroad . He offered the possibility to get this training in Italy, in order to be able to re-start the programme in Slovakia, when possible, in a safe way. This proposed study-visit of Slovak transplantation medical and nursing staff to Italy, not being strictly an activity foreseen in the project, should be considered as an "extra – Twinning" activity.
Bologna Liver Transplantation Centre was indicated as the potential place where to realize the goal of Italian purpose, because of the high number of liver transplants and quality of the clinical outcome.
The plan ,reported initially to MoH as a Letter of Intent,was developed as a potential common project in the following way: 1) training courses for Slovak physicians and nurses to be held in Bologna liver transplantation centre, with the possible financial support of EU structural fundings 2007-2013 for Slovakia, 2) transplantation of Slovak cirrhotic patients in Bologna liver transplantation centre, using Slovak donors, 3) use of marginal livers in Italy, when not used for Slovak cirrhotic patients.
Following this meeting , a two-days visit to Bologna liver transplantation centre was organized with representatives of Slovak Transplant Society ,with the agreement of MoH, in order to evaluate the facilities. Six slovak experts came to Bologna and they were the following: Mr Koller, Mr Kuba, Mr Hrusovsky, Mr Roland, Mr Laca and Mr Jarcuska.

A press-conference , held in Bologna, concluded this visit, reported on some local and , later, national italian newspapers and magazines.
Following this visit in Bologna at the beginning of March, the Slovak Transplant Society fully approved this potential plan of collaboration during a meeting held in Kosice on 14.04.07, with an own standpoint reported at the end of this report (see Annex 3).Moreover, Mr Nanni Costa (Italian PL) had a meeting on 23.03.07 at MoH with Mr Kluka and Mr Nagy- substituting Mr Hochel, discussing the results of the two-days visit and the possibility to develop an legal agreement between Bologna liver transplantation centre and slovak MoH about liver transplantation activities, under the supervision of Italian National Transplant Centre and the auspicies of Italian MoH.
Following this meeting, the Health Authority of Region EmiliaRomagna (where Bologna is located in Italy) and |Bologna Transplant Centre developed a possible legal agreement as a common project on liver transplantation to be offered to slovak MoH, which was discussed by RTA Mr Lauro and Mr Kluka (Slovak MoH) between end of March and end of May 2007 and officially presented to Mr Hochel (Slovak MoH) on June 2007. The MoH (represented by Mr Hochel) will evaluate the project during Summer 2007, making its remarks and discussing it again on September 2007 with IT PL Mr Nanni Costa in Bratislava , in order to achieve a possible common agreement on it.
This plan, was useful to the twinning project for the following reasons, even if it is clearly an extra twinning activity, outside the goal of the project:
1) By means of the audit, there has been acquired a clear picture of the real situation in Slovakia. This means that the audit was used not only in developing the other three components of the project, but was useful in order to promote new transplant activities as well, e.g. liver transplantation. The audit italian experts were invited to express their opinion to some potential liver transplantation centres that are about to be developed in Slovakia.
2) RTA was invited to Tale (area of Banska Bystrica), in order to discuss the liver transplantation issue at the national conference of hepatologists on 25.05.07. There was the opportunity to present the Italian project of potential collaboration on liver transplantation with slovak MoH and to discuss with the representative of Czech IKEM, Mr Vitko the possibility to integrate the Italian plan into the collaboration between Slovakia and Czech Republic on liver transplantation ,already existing since a long time.
3) Marginal donors were taken into account as potential liver donors to be offered abroad, if not used for Slovak cirrhotic patients.
Italy, through the Italian Gate to Europe in Rome, got 6 marginal livers from Slovakia for 6 cirrhotic recipients since two days visit of Slovak experts on March 2007: 2 livers went to Bologna, 2 to Modena ,1 to Ancona and 1 to Torino.
All these 6 recipients in Italy were transplanted and in good conditions after liver transplantation.
Other two marginal livers were offered by Slovakia to Italy but not used for problems related to the flight connection.
This fact has contributed to increase the total number of Slovak donors collected so far (close to 60 donors up to date since beginning of 2007): in fact, comparing to the same period of year 2006, the number of donors in Slovakia has raised notably, probably as a "twinning" effect and because of the new laws on transplantation discussed in the previous report.

- *Accreditation of Slovak transplant centers by Tw project audits*

This topic was discussed during the last monthly meeting (as previously reported), and the agreement was that MoH is free to take the option to use the Italian audits to give an accreditation to slovak transplant centres, even if it is not mandatory and foreseen inside the project. The accreditation of transplant facilities should strictly follow the national law and should be performed by competent national authorities.
Again, the main aim of the audits was to have a real picture of the transplant situation in Slovakia, in order to plan properly the following activities inside the twinning project.

- *Communication of all the partners in the TW project*

The way of communication between partners in this TW project should be improved, if possible: during the first Steering Committee Meeting it was already mentioned to the previous SPO (Ms Pikulova) and it has reinforced with new SPO, Mr Skorvaga. The use of emails or phone calls is welcome by everybody, but there should not be any "bridge" of communication between partners, and all Slovak and Italian partners should communicate directly each other after more than 6 months of activity together.
There were some changes during the course of the project, especially related to key-role persons from SK side: at the beginning of May the new SPO Mr. Skovarga was appointed and new SK Project Leader, Mr. Rasi was notified through Addendum no. 1 which entered into force on April the 3rd 2007. This is not a problem as far as the communication between the partners will be kept as high and good as possible, and consequently the continuity of the project will be fully ensured.

Recommendations

The development of a QMSGuide was advisable in order to replace old own quality systems guides inside transplantation centres and to foster the EU Directives. Still it will be necessary to apply it by means of training courses, as the newly designed Short and Medium term courses. It is highly reccomended to financially support Medium term courses by MoH, in order to obtain the maximum attendance by slovak trainees.
The old software needed to be updated and it will be realized by the project, taking into account that the hardware should be necessary as well in order to fully support the SW. Hardware modification has been elaborated and already submitted to Governemental Office.
SCOT needs to be empowered as well as the network between coordination and transplant centres, realizing a real "transplant community", interacting scientifically and medically.
Financial support needs to be foreseen in next years to support this transplant community.
Liver transplantation needs to be implemented in Slovak Republic: all possible agreements with other countries must be foreseen as just an initial step towards full independence of Slovakia on an own liver transplantation programme.

Section 3. Expenditure tables

Section No.	Name of services / goods purchased or direct costs	Date(s) of services	Supporting Document	Date of invoice	Breakdown and clarification	Amount paid in local currency (if applicable)	INFO-EURO exchange rate	Amount paid in EUR	Amount foreseen in original budget	Amount introduced by side letter no. 2	Amount charged to contingencies
1	**Resident Twinning Adviser Augusto Lauro (13 months)**										
	Basic salary	March-May 2007	salary slips		Gross salary			€ 9.170,33	€ 71.604,26		
	Non-wage labour costs (36,031 %)							€ 3.761,32	€ 25.799,73		
	6% of salary and non-wage labour costs							€ 775,90	€ 5.844,24		
	Total RTA remuneration							**€ 13.707,55**	**€ 103.248,23**		
2	**Resident Twinning Advisor Allowances**										
	Daily Allowances (50%) 13 months	March-May 2007	salary slips		March= 21 April= 14 May= 23			€ 5.075,00	€ 34.562,50		
	Allowances for RTA for first 30 days								€ 5.250,00		
	Health and accident insurance for RTA								€ 2.600,00		
	Accomodation	20 March-20 May 2007	apartament rent receipts	March-April				€ 1.400,00	€ 12.000,00		
	Excess luggage								€ 175,00		
	Estate Agent's Fee								€ 400,00		
	Travel to and from place of duty - RTA (one for each period of secondment)								€ 1.400,00		
	Monthly allowance for special economically priced return trips	February-March-April-May	RTA statements use of car		February= 550 € (not reported in the 1st quarter) March= 375 € adjusted to days worked April =225 € adjusted to days worked May= 425 € adjusted to days worked			€ 1.575,00	€ 6.050,00		
	Total RTA Allowances							**€ 8.050,00**	**€ 62.437,50**		
6	**Project Co-ordination/Management Costs**										
	Participation of PL/DPL in PSC							€ 250,00	€ 2.000,00		
	'Project Management Costs'							€ 375,00	€ 3.000,00		
	Per diems							€ 175,00	€ 2.100,00		€ 30,00
	International travel							€ 700,00	€ 2.800,00		€ 184,85
	Visibility costs[1]								€ 2.000,00		
	Audit certificate costs[2]								€ 4.000,00		
	Total Project Co-ordination/Management Costs							**€ 1.500,00**	**€ 15.900,00**		**214,85 €**

7	**PROJECT ACTIVITIES**											
	Component 1: elaboration of an audit analysis of the current situation in the field											
	Activity no. 1.4 Reports and networking activities											
	Expert fees 3 MS experts, 3 days each							€ 750,00	€ 2.250,00		
	'Project Management Costs'							€ 1.125,00	€ 3.375,00		
	Per diems (3)							€ 350,00	€ 2.100,00		60,00 €
	International travel							€ 1.696,34	€ 2.100,00		
	local travel								€ 500,00		
	RTA local travel							€ 151,70	€ 400,00		
	RTA per diem for missions outside Bratislava							€ 350,00	€ 350,00		€ 60,00
	Total Activity no. 1.4							**€ 4.423,04**	**€ 11.075,00**		**120,00 €**
	COMPONENT 2 "design and implementation of a unified quality management system"										
	Activity no. 2.1 elaboration of QMSG										
	Expert fees 3 Member State exp.,							€ 3.375,00	€ 3.750,00		
	'Project Management Costs'							€ 5.062,50	€ 5.625,00		
	Per diems (3)							€ 2.275,00	€ 3.150,00		390,00 €
	International travel							€ 3.712,14	€ 2.100,00	3500	
	Translation							€ 560,00	€ 2.800,00		
	Total Activity no. 2.1							**€ 14.984,64**	**€ 17.425,00**	**3500**	**390,00 €**
	Activity no. 2.2 provision of set of specialized trainings										
	6 MS Experts Expert fees Short term Training, 3							€ 2.250,00	€ 4.500,00		
	11 Expert, 2 x Medium Term Training, 2x4 days								€ 22.000,00		
	'Project Management Costs'							€ 3.375,00	€ 39.750,00		
	Per diems (3)							€ 1.575,00	€ 22.400,00		270,00 €
	International travel							€ 2.822,10	€ 19.600,00		€ 266,63
	Local travel							€ 150,00	€ -	€ 500,00	77,00 €
	Translation								€ 3.400,00		
	Printing								€ 2.000,00		
	Interpretation consecutive								€ 3.600,00		
	Total Activity no. 2.2							**€ 10.172,10**	**€ 117.250,00**	**€ 500,00**	**613,63**
	COMPONENT 3 development of a specific software										
	Activity no. 3.1 preparation of the unified information system										
	1 MS expert-5 days and 1 MS IT expert-8 days Expert fees							€ 500,00	€ 3.250,00		
	'Project Management Costs'							€ 750,00	€ 4.875,00		
	Per diems (3)							€ 350,00	€ 3.150,00		€ 60,00
	International travels							€ 700,00	€ 1.400,00		€ 48,51
	Translation							€ 440,00	€ 1.000,00		
	Total Activity no. 3.1							**€ 2.740,00**	**€ 13.675,00**		**108,51 €**
	Surplus status line after SL 2									775	
	OVERALL TOTAL WITHOUT ASSISTANT AND CONTINGENCIES							**€ 55.577,33**	**€ 470.835,73**	4.000,00 €	**1.446,99**

Section 4 ANNEXES

Annex 1

ONE DAY VISIT at SCOT-Bratislava (SK)

16.05.07

by Dr Daniela Peritore , MD

OCST Roma (CNT-Italy)

The Slovakia's graft allocation system is officially based on a model with two different levels, the regional level and the national level represented by the SCOT. The regional level is organized in four areas (Bratislava, Kosice, Martin, Banska Bystrica), each one presided by a local coordinating unit, that operates in full autonomy and independence. Usually, when donors become available at a primary-care hospital, they are moved to the referring local coordinating unit where all the test to evaluate the suitability of the donors and the organs and the HLA typing are performed. When ready, the local coordinating unit transmits by fax the results of the HLA typing and personal data of the donor to the SCOT. Then the SCOT elaborates a list of most HLA-compatible kidney recipients in the national waiting list. The kidneys are allocated according to principle of HLA-compatibility regardless of regional catchments area criteria. For other organs such as heart, liver, lungs, pancreas, intestine, there are not national programs of transplantation but, in case of suitable organ, the local coordinating units contact directly the only transplant centre existing in Slovacchia for heart, or the exchange organizations of foreign nations for other organs. At the last of the process the SCOT collects and stores the data concerning donors and transplants. But the SCOT doesn't play a role in control of the process of organ donation, in the evaluation of the donor and organ suitability, in the verification of a correct utilization of all available organs, neither is consulted to give a professional or scientific support to solve prospective problems.

In agreement with the other international experience, seems that a way to achieve good results is the cooperation between local, regional and national transplant coordinating centers. The transplant system works efficiently only if there is a National Centre that can support and manage the whole process of organ donation in cooperation with the regional coordinating units that

having a better knowledge of local factors, can implement operational policies covering all aspects of the donation/transplant process and at the same time guarantee the fairness, transparency and safety of the whole system. Therefore the Central Organs should guarantee the well-knowledge of the problems related to donation and transplantation, show ability in problem solving and also control the entire process. It'd be desirable the creation of a network enabling the fast communication of anamnestic, clinical and instrumental data relative to the potential donor. The SCOT should promote scheduled meeting with the regional coordinating units in order to create a community where to exchange know-how, to share common scientific protocols, to discuss approaches to improve the utilization of the marginal organs and to standardize the allocation procedure in the regions.

Annex 2

Ghirardini/Ridolfi REPORT

Report on the Site Visit at the Transplant Coordinating Centres of:
Bratislava (16-5-2007), Martin (17-5-2007), Kosice (28-5-2007), Banska Bystrica (29-5-2007)

Experts from the Italian National Transplant Centre: *Dr. Lorenza Ridolfi and Dr. Angelo Ghirardini*

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- **Goal of the "audit"**
- **How the "audits" at the 4 Coordinating Centres were carried out**
- **General observations**
- **Strengths and weaknesses of the 4 Coordinating Centres**
- **Conclusions**

Goal of the "audit"

To comply with the request for an analysis of the Slovak organization and the coordination of transplants, in the framework of the "Twinning Programme" between Slovakia and Italy, to pinpoint the educational needs of the network to set up and define the characteristics for the educational courses foreseen.

How the "audits" of the 4 Coordinating Centres were carried out

Each of the 4 coordinating Centres in the Slovak Republic has been examined, on an average of
3 hours each and a good relationship with the local coordinator was established.
In the table below are the local coordinators:

Date	Place	Participants
16-5-2007	Bratislava	M. Vateha
17-5-2007	Martin	J. Miklusica
28-5-2007	Kosice	L. Bena, R. Roland (+ 1 coordinator anaesthetist)
29-5-2007	Banska Bystrica	T. Sykora (+ il responsible anaesthetist)

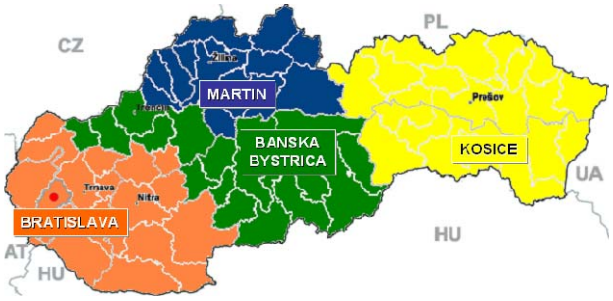
During the interviews we used a questionnaire, (annex 1, 11 pages) conceived by taking into account criteria to evaluate quality.
At the end of the interview we have examined the observations, questions and suggestions of the persons involved.

General observations

The intention of the Slovak Health Ministry to raise the number of donations and transplants count on the experienced professionals in donations and transplants.
The control visit did not include the national coordinating transplant centre (SCOT) which was visited by Doctor Peritore.
It was clear in the hospitals where the 4 coordinating centres are located that the identification of a coordinating centre and the role of coordinators is recognized by the health care authorities; in the different centres there are well-defined procedures and a shared on potential donors; the protection of the donor, the evaluation of the compatibility of the donor, the allocation of the organs and the retrieval of the tissues.
There is no homogeneity at national level of the above procedures and of reference documents.
A reference donor registry is available, where donor files are complete and well organized, especially regarding the will of the deceased (there are not always originals of virological report and blood groups which are mandatory by law; this can be obtained from the certified labs).
It is not always possible to carry out anatomopathological and special lab tests in 24 hours.
The coordination is based upon the voluntary professionals involved who only in Banska Bystrica are paid –albeit modestly - for what they do concerning donation of organs and tissues apart from their institutional duties. No economic incentive is foreseen for the local coordinator of peripheral areas.
Computerization of data related to donation is diverse in different areas and is not always referred back to procurement centres.
The cultural update of the local coordinators is very accurate, even if they have a frequent turn over.
The common characteristic of the 4 Centres is that they are very well-connected with the transplant centres of the hospitals. In Martin and Kosice, the local coordinator is a physician working in the transplant centre of the hospital. In Bratislava and in Banska Bystrica the coordinators are anaesthetists-resuscitators.

In the framework of the existing operations of a heart transplant centre, and a possible opening of one or more liver transplant centres, it would be advisable to reinforce the collaboration in the offer of organs in those 4 centres, also through the SCOT.
A bio-conservatory of organ and tissue serum is not foreseen.
It is the common opinion of professionals that have been interviewed that the new law of the Slovak Repubblic on donation has contributed to the rise in the register of potential donors?
A critical point is the lack of administrative assistance almost everywhere.
The presence of a national register of those awaiting kidney transplants, allows for the allocation of organs to the most compatible recipient.
An information campaign on donations from deceased donors has been addressed to the population.
There is no systematic dissemination of a report (national or local) of data on the activities.
There is a quality program to monitor deaths in ICUs only in Banska Bystrica.
Since the majority of the donors are young, tests to exclude prostatic neoplasia are not foreseen.
If the procurement centre considers a donor or an organ not to be suitable, it is not offered in the other centres in Slovakia or abroad, except when there is a surplus.

Strengths and weaknesses of the 4 Coordinating Centres



Bratislava

Strengths
Excellent protocol to evaluate the suitability of the donor, carried out in collaboration between the doctor in charge and the Coordinator.
Presence of appropriate competences able to retrieve the organs apart from kidneys and send them abroad.
Accessibility to the emergency labs 24 hours.

Weaknesses
Criteria for identifying potential "marginal" donors who are not taken into consideration or restricted (e.g. a donor over 40 is considered "marginal").
Medical examinations on the donor are carried out only on week days as well as echocardiography for potential heart donors and also biopsic exams that are prescribed in order to evaluate the safety of the donor and the quality of organs to be donated.

Request from the centres
Basic training courses for ; physicians on donation and transplants, setting up of a national campaign on the issue, courses related to communications for health care personnel in charge

of the relationships with the relatives of the potential donor, increase of the operative role and the functions to be carried out by the SCOT.
The lack of a clinical perfusionist when the donation is carried out can be considered a problem when executing the retrieval process.

Martin

Strengths
Every three months, the Coordinator carries out a control visit to the local coordinators of each of the 8 local hospitals.
The evaluation of the suitability is a multidisciplinary event.
Access to the emergency labs 24 hours on *ad personam* availability.
The coordination manages the urgent requests for heart transplants in Slovakia.

Weaknesses
There is only one doctor coordinating donations (24 hours and 365/365 days) and also carries out.
Institutional duties (surgeon of the kidney transplant centre).
Instrumental exams and biopsies, if indicated, are carried out only in daytime hours on working days, and in some cases the retrieval is postponed in order to carry out the exams.

Requests from the centre
Need of training courses for local coordinators in more peripheral areas in Slovak.
Need for the introduction of a national system in order to boost the local coordinators and health care personnel involved in donations and transplants.

Kosice

Strengths
Very well structured organization of the Coordinating Centre with partially dedicated personnel, but adequate together with nursing staff.
They have algorithms to identify and maintain the potential donors which are distributed and placed in ICUs of the hospitals.
Occasional retrievals also in more peripheral hospitals.
The evaluation process of the suitability of the potential donor is multidisciplinary.
Banking for 4 kind of tissues.
Greatest attention to information for citizens on the donation issue in collaboration with the Public Relation Office of the hospital (Campaign for kidney donations from living donors, conferences in schools).

Weaknesses
Feed-back report on the outcome of retrieval and transplants in the most peripheral areas, have identified the donor in a non-optimal way, but recurrent control visits to local coordinating centres. In each place there is a Key- person.

Requests from the centre
Opening of a biobank to store the serum of all the donors.
To give extra money to health care personnel involved in donations and transplants.
To create a network of local coordinators in peripheral areas, composed mainly of anaesthetists and internists.
Administrative personnel full time.
To raise the operability and functions of SCOT, in order to become a controller of the Slovak transplant system
To open a kidney Transplant Centre in Kosice, trained experts in the field can already be found there, they are young and would like to continue to carry out this activity. The local proximity with extra European countries, in the near future, could be a core institution for patients and organs from abroad.

Banska Bystrica

Strengths
Sufficient personnel in the centre, with a part time secretary (1day/week).
Only example in the country of personnel given extra money for the activities carried out.
Support, also in loco, given to the peripheral coordinating in the evaluation of the donor.
Follow-up in peripheral institutions on donations and transplants.
Tissue bank integrated with the coordinating centre, where the documents related to the retrievals are sent.
Experience in multi-organ transplants, combined kidney transplants, previous experience in kidney transplants.
Good potential for donations, because the reference area hospital has 31 TI beds.
Responsibility on donor suitability undertaken by the local coordinator.
Emergency lab operator availability.
All the local coordinators have the TPM diploma and 2 of them, the European certification as donor coordinators.
Operability of transplant programs for kidney from living donor, also in cross over modality and combined kidney/pancreas.

Weaknesses
Only one surgeon for liver transplants, therefore organs are not offered to other institutions which is different to Prague.

Requests from the centre
Improve transparency in organ allocation in Slovakia.
To restore enthusiasm: raise organ donation and transplants and the opening of new centres would be a good boost.

Conclusions

From what is written above, the necessity to improve the network of the donation coordination, in a system having already good organizational practices but not homogeneous, is clear.
The functions of the SCOT, area and local coordinating centres should be divided and assigned. Approximately these could be the following, but only for Slovak personnel who understand the situation, could assign them.

Functions

national	waiting list management coordination of setting up national guidelines for inserting patients on the waiting list coordination of setting up national guidelines for organ allocation coordination of the setting up national guidelines for organ and tissue retrieval activities periodic control visits to donation structures, reference centres, transplant centres and tissue banks management of organ allocation in urgent cases and for national programmes (e.g. Paediatric) coordination of national guidelines to control the quality of immunology labs coordination of guidelines on safety of organ tissue and cell donors definition of parameters of quality and results of transplant structures promotion, management and coordination of relationships with foreign institutions in order to foster organ, tissue and cell exchange campaigns aimed at the general public on the topic collection of the feed-back on donations and transplants in the national network collection data related to brain-damaged people at national level management of the national system
area coordination	has its own waiting lists pertaining to the area coordination of donation activities allocation of organs taking in to account the national guidelines coordination of transport related to the donation and transplants. information campaign for the people living in the area management of the education and training of professionals in compliance with national guide-lines management of the feed back within the area network care of the feed-back on donations and transplants on the local network analysis of data related to the brain-damaged people in the area coordination of information in the area

local coordination
- communication of data of potential donors
- registration of documentation on donations and retrieval
- follow-up of the process of donation-retrieval in each phase
- relationships with donors relatives
- registration of brain-damaged people
- information campaign for the population at local level

Potential donations of the Slovak Republic and optimization strategies

Area	Population	%
Bratislava	1,911,445	35.5
Banska Bystrica	1,046,745	19.5
Kosice	1,555,980	28.9
Martin	865,285	16.1
Total	**5,379,455**	**100.0**

The objective is to reach 30 donors used p.m.p. who would permit the execution of over 200 kidney transplants, at least 120 liver transplants and 30 heart transplants a year in a country which has 5 million inhabitants.
For this purpose, it is indispensable to provide national financing aimed at:
Each local coordination (peripheral branches) together with an officially nominated local coordinator for each hospital equipped with potential donor re-animation, thus defining the functions
4 coordination areas after defining the functions and providing medical, nursing, administrative dedicated personnel (even if non full-time)
Hospitals identified as the seat of new Transplant Centres
Hospitals as tissue and cell banks
Peripheral hospitals where organ withdrawal can be carried out in compliance with Slovak laws (autopsy)
Hospitals identified as national referents for immunegenetics related to transplants, the donors' safety, the quality of the organs donated (objective: emergency services available 24 hours)
Informing the population in a wide-spread manner in collaboration with voluntary associations

A further tool to increase donations is the evaluation of the current "marginality" criteria of donors which can be applied through the training programme provided in the ambit of the Twinning as well as the sharing of the national guide-lines about the compatibility of donors and organs which is in progress in the Slovak Republic.

Transport

In the light of an increase in the donation and transplant activities in the Slovak Republic and the subsequent increased organ exchange with other European countries, the logistic conditions of airport is good as you can see in figure 1. The Bratislava, Kosice and Banska

Bystrica centres are equipped with the Poprad or Sliac airports which can be reached in an hour-drive.
The desired increase in donations and the likely opening of new Transplant Centres (at least 1 or 2 liver transplants) will result in further potential organ exchange between the 4 Slovak centres.
In figure 2, the distances in kilometres between Slovak Transplant Centres and the driving times which are broadly acceptable for the exchange of kidneys currently activated in the country.
With regard to the implementation of the donation-withdrawal-transplant network in Slovakia, further transport improvements and rationalization can be studied in depth (we know that from time to time, insurance companies funded some of the hoverplane transport from/to Banska Bystrica).

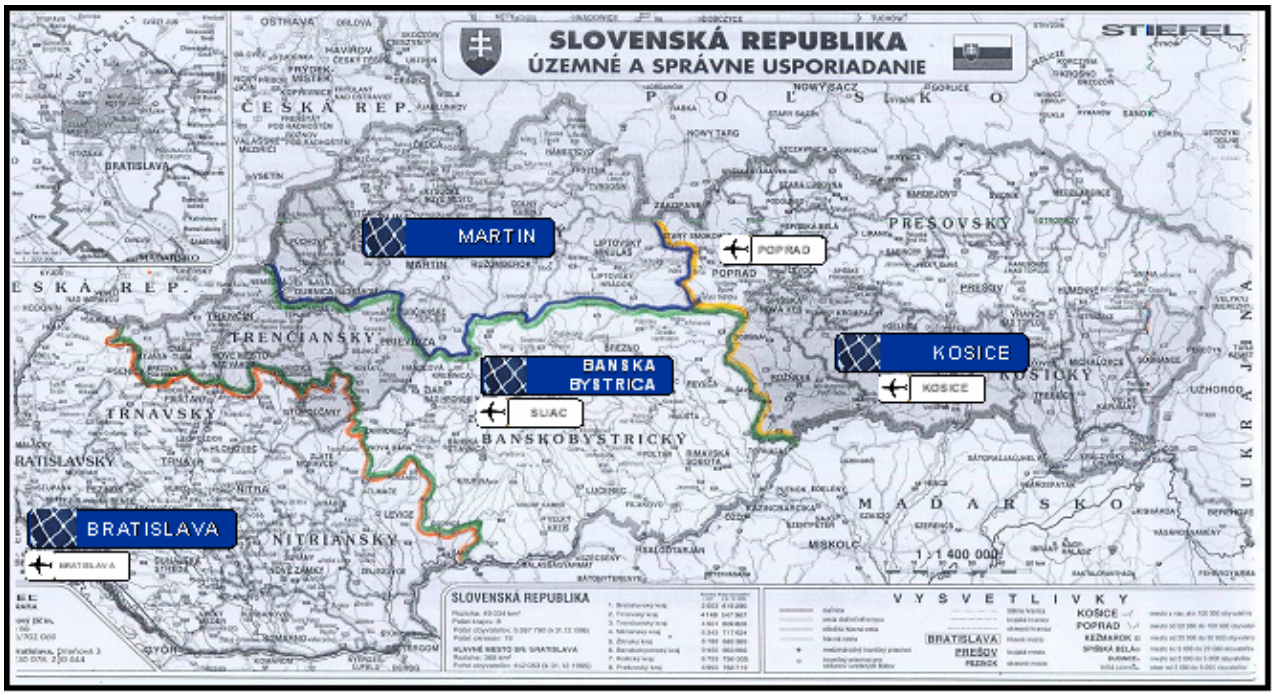


Fig. 1

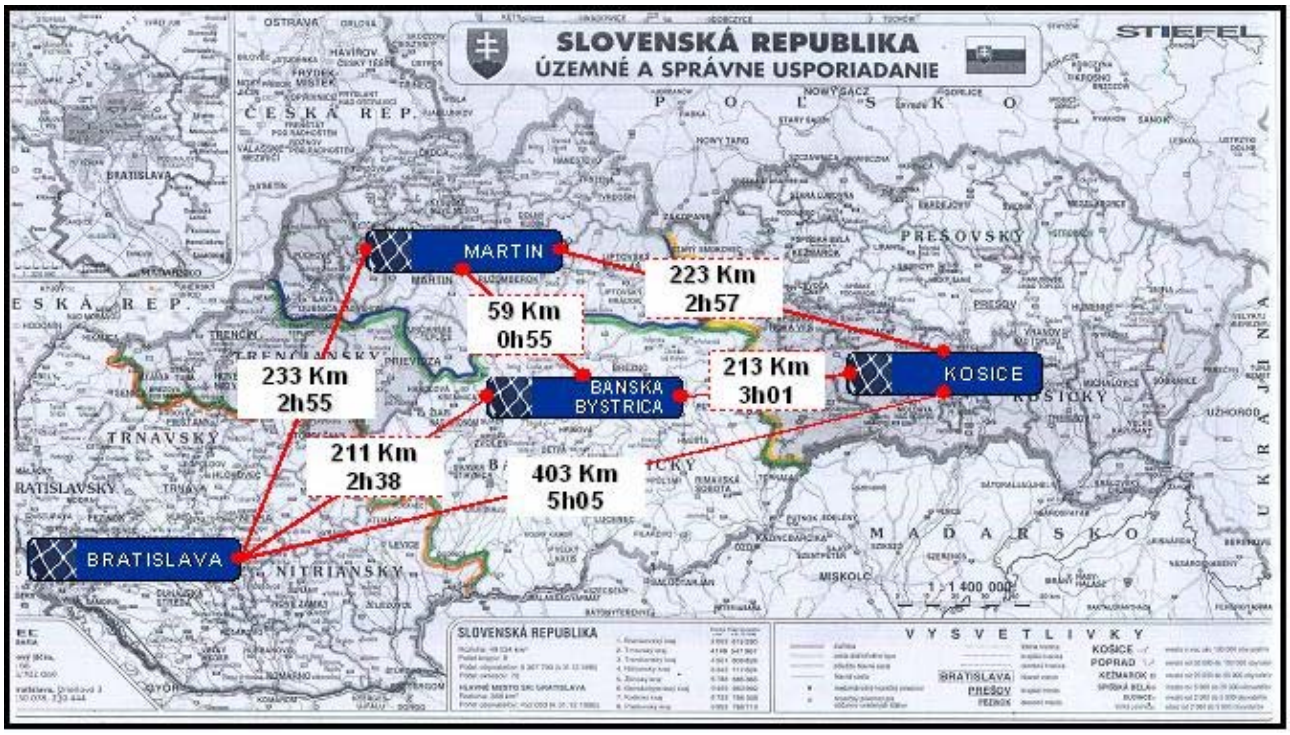

SLOVENSKÁ REPUBLIKA
ÚZEMNÉ A SPRÁVNE USPORIADANIE
STIEFEL
MARTIN
223 Km
2h57
59 Km
0h55
233 Km
2h55
213 Km
3h01
BANSKA
BYSTRICA
KOSICE
211 Km
2h38
403 Km
5h05
BRATISLAVA
TRNAVSKY
NITRIANSKY
PRESOVSKY
KOSICKY
MADARSKO
UKRAJINA
POLSKO
CESKA REP.
SLOVENSKÁ REPUBLIKA
VYSVETLIVKY

Fig. 2

Education

In the ambit of the Twinning, all the indications about the training needs of the Slovak health personnel have been registered.
It would be useful to hold theoretical training courses in the Slovak language mainly with Slovak teachers as well as to carry out role playing sessions in small groups during which Slovak professionals can propose not only hypothetical future rules concerning the functions to be attributed at local, area and national level, but also related to the organization of the coordination for donations and transplants, and least but not last, the organ allocation criteria.
Obviously, the Italian colleagues wilI be available to respond to eventual questions and to stimulate the audience.

Angelo Ghirardini and Lorenza Ridolfi

Bologna, 1° June 2007

Annex 3

Annex 3 is reported as part of the "Liver Transplantation: the extra twinning activity" and its aim is only informative.

Standpoint of STS
(Slovak Transplant Society committee to the Letter of Intent)

STS Committee discussed on 12.04.2007 the Letter of Intent which was sent to the Minister of Health by the general manager of the St.Orsola-Malpighi Hospital (Bologna-Italy).
The Committee appreciates the proposal of the Italian partner, because it increases the possibilities of the Slovak transplantology. Because of the long good and financialy advantegous cooperation with Czech partner, we implicate the collaboration with the Italian partner by not being the exclusive partner. According to the Slovak law, the contract has to be signed by legal subjects - medical centres realizing transplantations and procurement.

MUDr. Robert Roland
Prezident STS

Kosice, 14.4.2007

Slovenská transplantologická spoločnosť
Stanovisko výboru STS k Letter of Intent

Výbor Slovenskej transplantologickej spoločnosti prerokoval 12.4.2007 Letter of Intent zaslaný ministrovi zdravotníctva SR generálnym manažérom St.Orsola-Malpighi Hospital (Bologna-Italy).

Výbor víta návrh talianskej strany, pretože rozširuje možnosti slovenskej transplantológie. Vzhľadom však na dlhodobú dobrú a finančne výhodnú spoluprácu s českou stranou podmieňujeme spoluprácu s talianskym partnerom tým, že nebude exkluzívnym partnerom. V súlade so slovenskou legislatívou zmluvy musia uzavrieť právne subjekty - transplantácie a odbery realizujúce zdravotnícke zariadenia.

Výmenu pečení odporúčame realizovať cestou ETN.

MUDr. Robert Roland
Prezident STS (Košice, 14.4.2007)

Annex 4

- **Hardware required for the project**

Information system aplication description:
Central aplication accessible non stop on line through WEB

Servers:

Database server
dual core processor (or possibility to extension to two procesors)
8 GB RAM extendable to 32 GB
disc field RAID
disc capacity. 300 GB
backup data tape 72 GB
network cards
UPC 1000 W

Estimated price: 6,000 Euro

Transaction server
dual core processor (or possibility to extension to two procesors)
8 GB RAM extendable to 32 GB
disc field RAID
disc capacity. 300 GB
network cards
UPC 1000 W

Estimated price: 3,100 Euro

Firewall server
dual core processor (or possibility to extension to two procesors)
8 GB RAM extendable to 32 GB
disc field RAID
disc capacity. 300 GB
network cards
UPC 1000 W

Estimated price: 3,100 Euro

Cisco router – for LAN
20 users

Estimated price: 1,400 Euro

Working station for network administrator

PC + LCD monitor 19'

Estimated price: 1,400 Euro

Estimated price TOTAL: 15,000 Euro

- **Standard Summary Project Fiche for the Transition Facility**

1. Basic Information

1.1 CRIS Number:

1.2 Title: **Improvement of the safety, quality and availability of organs, tissues and cells for transplantation.**

1.3 Sector: Health

1.4 Location: Bratislava, Slovak Republic

2. Objectives

2.1 Overall Objective(s):
Proper implementation of the Directive 23/2004/EC on setting standards of quality and safety for the donation, processing and distribution of human tissues and cells in the Slovak Republic.

2.2 Project purpose:
Introducing quality management for organ transplantation, tissue and cell banking to assure the highest possible level of public health protection.

2.3 Justification
It is in line with 2003 Comprehensive Monitoring Report on Slovakia's preparations for membership:

Social policy and employment: *Efforts should continue in order to develop a health monitoring system with a view to obtaining health data and indicators comparable with the Community health monitoring system*.

3. Description

3.1 Background and justification:
The availability of human organs, tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use. It is necessary to provide information at national level on the donation of tissues, cells and organs based on the theme 'we are all potential donors' (Directive 23/2004/EC). As there is a need to ensure the availability of tissues and cells for medical treatments, the Slovak Republic should provide the donation of tissues and cells, including haematopoietic progenitors, of high quality and safety, thereby also increasing self-sufficiency in the Community.

The transplantation of human organs, tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases. *The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State nonetheless carry the same guarantees as those in their own country* (Directive 23/2004/EC).
All necessary measures need to be taken in order to provide prospective donors of tissues and cells with assurances regarding the confidentiality of any health related information provided to the authorized personnel, the results of tests on

their donations, as well as any future traceability of their donation. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data applies to personal data processed in application of Directive 23/2004/EC. Article 8 of that directive prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down.

An adequate system to ensure the traceability of human tissues and cells should be established. All the data concerning donation, procurement, preservation, storage, distribution of tissues and cells shall be stored for 30 years.

The Ministry of Health SR, as a central state administration body in the health sector is responsible for implementation of Directive23/2004/EC in general and it has appointed, by its decision, tissue establishments to be responsible for direct implementation and execution of that Directive in the praxis.

In the area of tissue, cells and organ procurement and transplantation there are two main types of organizations: 1) tissue establishments and 2) organ transplantation centres.

The first tissue establishment in the Slovak Republic was linked to Ružinov General Hospital in Bratislava and started its activity in 1988. The list of currently existing tissue establishments under the competence of the Ministry of Health SR is as follows:

- Central Tissue Bank, University Hospital Ružinov, Bratislava, multi-tissue bank
- Associated Tissue Bank, University Hospital and Medical School, Košice, multi-tissue bank
- International Eye Bank, Petržalka University Hospital, Bratislava , eye bank
- International Eye Bank, F.D.Roosewelt Hospital, Banská Bystrica, eye bank
- Haemopoetic Cell Banks (HPC banks) - 4 in Bratislava, 1 in Banska Bystrica, 1 in Martin, 1 in Kosice, 1 in Presov

In addition, there are non-governmental and private organisations such as:

- Slovak Register of Cord Haemophoetic Cells (EUROCORD), Bratislava, cord blood bank
- Centers for assisted reproduction and sperm banks

As regards organ transplantation centres, all of them are under the responsibility of the MoH as follows:

- Slovak Centre for Organ Transplantation – Slovak Medical University (SCOT) with 5 Regional Transplantation centres

1. Transplant centre University Derer's hospital, Bratislava (kidneys, liver)
2. Transplant centre, Slovak institute for heart diseases, Bratislava, (heart)
3. Transplant centre University hospital, Martin (kidneys)
4. Transplant centre Roosewelt hospital, Banska Bystrica (kidneys, pancreas)
5. Transplant centre, University hospital, Košice, (kidneys)

The public awareness towards organ, tissues and cells donation is very low in Slovakia. The main reason for this is a lack of public awareness among health staff and medical personnel and a lack of financial resources. The result is a very low rate of donations, which achieves annually less then 20 donations per 1 million of inhabitants in organ transplantation.

The main reason why problems such as a lack of donors and long waiting lists for organ donations occur is the presently unsatisfactory information system that is not unified, and interconnected, neither between the tissue establishments, nor with the Central donor and non-donors register located at the SCOT in Bratislava. This means that for example information about a possible donor in one tissue establishment is not at disposal in the whole network. Secondly, the information system for organ transplantation does not include the requirements of tissue and cell establishments and it is not compatible with the requirements of the Directive 23/2004 EC. A central information system managing waiting and donor lists for organ donations is already 8 years old and needs to be upgraded. The required data confidentiality, data protection, and data storage time cannot be as yet fully assured.

Additionally, each tissue establishment elaborated its own quality management system, which mostly does not conform to contemporary regulatory and quality requirements of the European Communities. These systems strongly need to be unified as well and updated according to the latest EC Directive 23/2004/EC.

Regarding the institutional framework of the quality control, it is monitored by national authorities: Slovak National Accreditation System (SNAS) and State Institute for Drug Control (SIDC). SNAS controls the good laboratory praxis, and SIDC is responsible for good manufacturing praxis.
Establishments have to fulfil the accreditation criteria as ruled by the above-mentioned authorities. The project will give a framework for compatibility of national and EC requirements for safety and quality management in field of organ tissue and cell transplantation.

3.2 Linked activities:

2003 Public Health Programme - „European Quality System for Tissue Banking" - one of the Slovak tissue establishments – the Central Tissue Bank of the University Hospital Ružinov in Bratislava - participated in this project led by Hospital Clínic i Provincial de Barcelona, Spain. This project is focused on the adoption and establishment of minimal requirements for the quality management of tissue banking and tissue establishments in Europe, whereas the here presented project aims at the implementation of the EC Directive 2004/23/EC to the specific conditions in the Slovak health care system. Mentioned project is in very early stage of implementation.

3.3 Results:

3.3.1. Audit report elaborated

The report will summarize the results of an audit of the existing expertise, human resources and technical conditions related to the implementation of quality systems in all participating institutions under the MoH's responsibility and will provide set of recommendations for possible improvements.

3.3.2. Quality management systems for tissue and cell establishments and organ transplantation centres developed and introduced

A unified quality management system for all Slovak tissue and cell establishments, to be compatible with the requirements of the Directive 23/2004/EC, will be developed according to the specific needs of both tissue establishments and organ centres. This system will consist of two parts:

3.3.2.1. Quality management system guide (QMSG) developed

A QMSG will be developed for the overall implementation of quality aspects in tissues, cells and organs establishments. It will have two main parts – a general and a specific one. The general part will cover the following points:

- general principles of good clinical and laboratory practices
- general guidelines for QMS (Quality Management System)

and will be unified for both tissues and organs.

The specific part will cover:

- standard operating procedures
- training and reference manuals for staff
- reporting forms
- donor records and follow up forms for the transplanted organs, tissues and cells

separately for tissue and cells and for organs.

All the documentation should be produced in order to enable inspections by the competent authority or authorities, and to ensure traceability in accordance with Article 8 of the Directive 23/2004EC.

3.3.2.2. Tissue establishments and transplantation centres staff trained

The employees of tissue establishments and transplantation centres will be trained according to the new training manuals developed under point 3.3.2.1. The training will be provided for professional staff of all institutions (mentioned in background).

3.3.3. Unified information system for transplantation centres, tissue and cell establishments developed, implemented and tested

The information system will be developed by TA. It shall be based on the requirements, which have been set up by the Directive 23/2004/EC, and implemented into the Slovak conditions for final use by both tissue and cell and

organ transplantation services. The information system will be compatible with similar information systems used in other EC countries. After its development and installation at the beneficiary institution, the short pilot testing will be provided by the twinning team together with the staff of the beneficent institution.

3.3.4. Guidance brochure and information leaflet on tissue, cells and organs donation produced

To better explain the impact of Directive 23/2004/EC to the medical professionals the development of guidance brochure is necessary. It will contain an explanation of Directive 23/2004/EC, the relevant Slovak legislation, the reasons of donation of tissues, cells and organs and relevant information on how to approach the public, how to increase public awareness, and how to detect potential donors actively. More information will be provided on donor screening and proper management of the detected donors. Additionally, an information leaflet for the public will be produced.

3.4 Activities:

3.4.1. Elaboration of an audit analysis of the current situation in the field (2.-4. month)

MS experts in the first phase of the project will execute an audit analysis of all workplaces of tissue, cells and organs institutions under the MoH's competence involved in the project. The audit will cover human resources and equipment of audited facilities. The audit report will include also recommendations, specified according to each workplace visited.

3.4.2. Design and implementation of a unified QMS (5.-9. month)

3.4.2.1. Elaboration of QMSG (5.-8. month)

A working group will be established at the recipient institution including Member State experts, the MoH and representatives of SCOT, regional transplantation centres, and tissue establishments. It will be composed of two subgroups, which will be able to work independently. One of the subgroups (SG1) will be composed of professionals working in organ transplantation centres, the other one (SG 2) of professionals from the tissue establishments. Both subgroups will collaborate closely, and the output of the work of these subgroups will be one consensus material – a QMSG, including training materials. All materials, the QMSG included, will be produced in Slovak and English language.

3.4.2.2. Provision of set of specialised trainings (9. month)

Consequently, after production of the QMSG, the MS experts will provide a set of 2 different trainings. The first set of trainings, oriented on general principles, will last 2 days and will be provided for employees of all Slovak institution in the field of tissues, organs and cells together. The training will cover the presentation of relevant quality management systems in the EU

and explain the process of implementation of the newly proposed system suggested in the QMSG's general part.
The second set of trainings will consist of two 4-days trainings: one for tissue establishments' employees and the other one for organ transplantation centres employees. These specific trainings will provide an explanation of the specific parts of the QMSG according to each group's specialisation.
Both sets of training will be provided for together about 100 employees of tissue and cells establishments and organ transplantation centres.

- **Development of a specific software and procurement of equipment for SCOT (9. – 24. month)**

3.4.3.1 Preparation of the unified information system. (9. – 11. month)
The same working group as in activity 3.4.2.1., supported by an IT specialist forming part of the twinning team (see under means), will prepare complete software specification for a unified information system for transplantation centres, tissue and cell establishments. . The working group will define the conditions, outputs and inputs and functionality of the special software, data model, and structure, hierarchy and user rights in the information system. Special attention will be given to data and network safety and encryption of personal data. The system will cover the following characteristics:

- Establishment of a web-based information network that will allow submission and reading of data for all participating organisations with defined specific access rules
- Establishment of a central registry serving for all the Slovak tissue establishments and transplantation centres
  - Establishment of a system for identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8 of the Directive 23/2004/EC.
  - Introduction of a single European coding system to provide information on the main characteristics and properties of tissues and cells implemented into Slovak tissue and cell establishments, following the Technical Requirements to the Directive 23/2004/EC
  - Compatibility with the bar coding system which is planned to be introduced for tissue and cell establishments by the EC, and shall be specified in the Technical Requirements
  - Access to relevant parts of the registries of the SCOT
  - Introduction of complex record keeping of all the tissue and cell establishments
  - Acting as an information exchange system between the tissue and cell establishments in the Slovak Republic pertaining availability of tissue and cell grafts, adverse events and serious adverts events reporting
  - Acting as information exchange between donor detection organizations and tissue and cell establishments

The SW specification will also include detailed description of requirements on the TA experts and TA company, that will develop the unified software.

Beside this, the MS IT expert will also prepare the system of assessment and evaluation criteria that will be applied when evaluation of the service tender, together with the recommendations how to control particular phases of the SW development process.

3.4.3.2 Development of software (12. – 22. month)

The unified information system will be developed and installed according the prepared specification together with application development software within the TA contract. This activity will also include the training of SW users from beneficiary institutions that will be provided by the Technical assistance within the same TA service contract.

3.4.3.3 Procurement of the special equipment for SCOT to ensure the high quality of unified information system (10. - 15. month)

The SCOT will be equipped by new hardware to ensure the sufficient capacity for data storage and information system performance (Specification in annex 4). The hardware will ensure all the requirements for data and system safety as well as the functionality and accesibility of the system for multiple users using WEB access.
This activity will be provided by one supply contract.

3.4.3.4. Pilot testing (23. – 24. month)

The RTA together with the IT expert will assist to the beneficiary and will provide the consultancy services during the testing phase of the new developed SW.

3.4.4 Preparation and development of the guidance brochure and the leaflet (7. .-9. month)

The aim of the brochure is to be the tool of better coordination and management of organs, tissues and cells donations, and will be used by medical professionals and transplant coordinators. The brochure will be prepared by the twinning experts and 1000 copies will be printed within the project budget.

In addition to the preparation of the above-mentioned guidance brochure for tissue establishments' professionals, an information leaflet for the public will be prepared (in case nothing comparable already exists in the EC, which could be translated into the Slovak language in the scope of this project). Both materials will be printed in Slovak language.

MEANS:

The project will be implemented in the framework of one twinning contract, one technical assistance contract and one supply contract.

Activity 3.4.1, 3.4.2, 3.4.3.1., 3.4.3.4. and 3.4.4. will be implemented in the framework of the twinning contract and its duration will be 13 months.

Activity 3.4.3.2. will be provided in the framework of a service contract.

Activity 3.4.3.3. will be provided in the framework of a supply contract.

In the framework of the twinning contract one RTA is envisaged, together with a pool of short-term experts.

The RTA should fulfil the following criteria:

- must have proven team leading experience in working with international teams
- will come from an institution equivalent to beneficiary institution
- must have perfect knowledge of Directive 23/2004/EC (knowledge of the practical implementation is an advantage)
- will perform professional and managerial supervision over the entire project
- university education in related field (medical doctor is preferable)
- at least 10 years of experience in safety, quality and availability of organs and /or tissues and cells for transplantation
- excellent knowledge of English and good communication skills
- must have experience in the international cooperation within the exchange of tissues and cells

The RTA should be responsible for:

- coordinate partial tasks of the project, sequence their realisation
- to coordinate pool of STEs
- to provide the requested audit, including analysis, on the spot visits and other
- coordinate and professionally participate in working group and also in SG1 and 2,
- in cooperation with pool of STE and working group to elaborate QMSG
- elaborate the detailed structure of the entire QMSG
- prepare and produce all training materials
- together with STE to provide both sets of trainings requested
- brochure and leaflet preparation and printing
- together with pool of STE to develop the text materials for both publications
- realisation of the pilot testing

The RTA will be accompanied during his/her secondment with an RTA assistant

- Must have excellent knowledge of English and Slovak language
- Good communication and organisation skills
- Previous experience in working with terminology in medicine and quality systems is preferable

The RTA will be supported in the activity 3.4.2. with following short-term experts:

STE 1 and 2 - Short-term experts for the development quality management system:

- must have experience with the development of quality management system for transplantation centres and/or tissue and cell establishments (both from different areas)
- skilled in usage of different quality standards and systems
- both will come from an institution equivalent to beneficiary institution
- both must have 5 years of the relevant working experience
- excellent knowledge of English and good communication skills

These experts will be responsible for the following issues:

- will participate in working group and in cooperation with RTA will lead one of the subgroups (SG1, SG2)
- in cooperation with RTA to elaborate the QMSG
- in cooperation with RTA will provide general as well as specific trainings (both sets)
- they may assist RTA in audit report elaboration (under activity 3.4.1.)

STE 3 – short-term IT expert for the development of specific software specifications (activities 3.4.3.1, 3.4.3.3.):

- he/she must have experience with development of similar software for data confidentiality, data protection, and required data storage time
- he/she will min. 5 years of the relevant working experience
- excellent knowledge of English and good communication skills
- he/she must have university degree preferably in IT
- should be experienced in database technology

This expert will be responsible for the following issues under activities 3.4.3.1, 3.4.3.3.:

- in cooperation with RTA managing the working group for software specification
- he/she will develop the Terms of Reference for unified SW, required application development software, system of assessment and evaluation criteria, recommendations how to control particular phases of the SW development process.
- in close cooperation with working group
- he/she will be member of working group for software specification
- he/she will participate and advice during the pilot testing phase

3.5. Lessons learned:

The main lesson learned from PHARE projects in the health sector is the good experience and validated model of management and coordination on the level of the Ministry of Health. The managing structure that was successfully tested is to have overall coordination at the ministerial level (also because the recipient institutions are subordinate of the MoH SR) and the professional guidance is on the recipient level. Project managers from Project Unit of Foreign Aid of MoH SR actively manage and in closely cooperation with MS experts and Slovak recipient institutions prepare and ensure all activities and organizational issues. Projects, which MoH SR managed were successfully finished and objectives and results were achieved, e.g. PHARE No. 2002/000.610-02 "Ensuring Preparedness of the Slovak Public Health Insurance System to apply to Acquis on Coordination of Social Security Schemes" etc

There were no recommendations made during previous interim evaluation that might be applied to this project.

From all institutions involved in this project, only MoH has its own experience with PHARE project management and those projects were evaluated as successful.

Central Tissue Bank implemented only scientific projects financed by Ministry of Health covering the validation of new methods of transplantation. They learned, it is

necessary to include and cooperate with number of other workplaces and laboratories to use their specific knowledge, experience.

4 Institutional Framework

The Ministry of Health SR (MoH SR) is the beneficiary institution and partner in the project. It will have the overall responsibility for the management and control of the project. Tissue and cells establishments and transplant centres will be the recipients of the project benefit.

Monitoring of and supervision over the progress and development of the entire project will be provided by a Steering committee (SC), which will include representatives of the MoH SR, Central Tissue Bank, the Twinning partner, Office of Government SR and CFCU.

The Project leader on the Slovak side will be:
MUDr Richard Raši, MPH
University Hospital Bratislava
Ružinovská 6
826 06 Bratislava
Tel.: +421 2 4823 4645
e-mail: rasi@fnspba.sk

SPO
Mr. Edmund Škorvaga
Ministry of Health of the Slovak Republic
Limbova 2
Bratislava 837 52 Slovakia
Tel.: +421 2 59373 308
Fax: +421 2 54776 051
E mail : edmund.skorvaga@health.gov.sk

The Project manager responsible for the content of the project will be:
Ján Koller, M.D., CSc
Head, Teaching Department for Burns and Reconstructive Surgery
Central Tissue Bank
University Hospital Bratislava Ruzinov, Ruzinovska 6
821 02 Bratislava, Slovak Republic
Tel/Fax : 00421/2 4333 6741
E-mail: koller@nspr.sk; jankoller@hotmail.com

Other person relevant to the project on behalf of the recipient:
Daniel Kuba, MD, PhD.
Head Slovak Centre for Organ Transplantation
Slovak Medical University
Limbová 12

Bratislava 837 52, Slovakia
Tel: 00421 2 59369342, Fax: 00421 2 59369 379
E-mail: daniel.kuba@szu.sk

5 Detailed Budget

€M	**Transition Facility support**			**Co-financing**			**Total cost (TF plus cofinancing)**
	Invest-ment Support	Institu-tion Building	**Total Transition Facility (=I+IB)**	National Public Funds (*)	Other Sources (**)	total co-financing of the project	
Twinning (contract 1)		*0,500*	*0,500*				*0,500*
Technical Assistance (contract 2)		*0,350*	*0,350*				*0,350*
Supply (contract 3)				*0,015*		*0,015*	*0,015*
Total		*0,850*	*0,850*				*0,865*

Note TRANSITION FACILITY expenditure for equipment should be put under Investment Support

(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises
(**) private funds, FIs loans to private entities

6. Implementation Arrangements
6

6.1. Implementing Agency

Ms. Silvia Matúšová
Acting CFCU Director/PAO
Štefanovičova 5
817 82 Bratislava 15
The Slovak Republic
Phone: +421 2 5958 2545
Fax: +421 2 5958 2559
e-mail: silvia.matusova@mfsr.sk

6.2. Twinning

The institutional twinning partner will be the Ministry of Health of the Slovak Republic, responsible for the overall supervision of the project.

National Contact Point for Twinning involved in Twinning projects management:
Mrs. Jana Minarovičová
Office of Government SR
Námestie slobody 1
813 70 Bratislava
Tel.: 00421/2 57 295 514
E-mail: jana.minarovicova@government.gov.sk

The Ministry of Health will cooperate in project implementation with the Central Tissue Bank and Slovak Medical University, which will be the recipient of the project.
The twinning experts will be deployed at the office of the Central Tissue Bank.

Contact person: Ján Koller, M.D., CSc
Head, Teaching Department for Burns and Reconstructive Surgery
Central Tissue Bank
University Hospital Bratislava Ruzinov, Ruzinovska 6
821 02 Bratislava, Slovak Republic
Tel/Fax : 00421/2 4333 6741
E-mail: koller@nspr.sk; jankoller@hotmail.com

6.3 Non-standard aspects

EDIS procedures and the rules of the Twinning Manual will be strictly followed.

6.4 Contracts

The project will be implemented with the following contracts:
Twinning contract: 0.500 mil €
Technical assistance (SW): 0.350 mil €
Supply (equipment): 0.015 mil €

7. Implementation Schedule

7.1 Start of tendering/call for proposals: 2nd Q 2005
7.2 Start of project activity: 4st Q 2006
7.3 Project completion: 4th Q 2008

8. Sustainability

Relevant policies and regulations of the Slovak Government ensure that all activities funded under the scheme will yield results that comply with the European Union norms and standards. Governmental funding of the operation and maintenance of the project is ensured.

9. Conditionality and sequencing

The project implementation will include the following milestones:

audit analysis report
QMSG developed and issued
training of relevant staff for unified quality management system
software specification prepared by MS experts in cooperation with the working group
software development and installation and equipment providing
SW training of the staff
preparation of brochure and leaflet, printing

Annexes to project Fiche

- Logical framework matrix in standard format (compulsory)
- Detailed implementation chart (compulsory)
- Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
- Hardware required

Transition Facility log frame

LOGFRAME PLANNING MATRIX FOR Project	Programme name and number	
Improvement of the safety, quality and availability of organs, tissues and cells for transplantation.	Contracting period expires 15 December 2007	Disbursement period expires 15 December 2008
	Total budget: € 0.865 million	TF budget: € 0.865 million

Overall objective	**Objectively verifiable indicators**	**Sources of Verification**	
Implementation of the Directive 2004/23/EC on setting standards of quality and safety for the donation, processing and distribution of human tissues and cells in the Slovak Republic	▪ all facilities included in this project accredited by the end of the 2007, fulfilling the requirements of the Directive 2004/23/EC	accreditation certificate	
Project purpose	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Introducing quality management for organ transplantation, tissue and cell banking, to assure the highest possible level of public health protection	increasing of the number of real donors om indicated donors by 10% decreasing of the number of insufficient rgans by 5 %	reports produced by the unified formation system internal evidence of Central issue Bank regular annual statistic reports repared by Central Tissue Bank	consistent keeping of the related islation
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**

1. Audit report elaborated 2. Quality management systems for tissue and cell establishments and organ transplantation centres developed and introduced: 2.1 Quality management system guide (QMSG)developed 2.2 Tissue establishments and transplantation centres staff trained 3. Unified information system for transplantation centres, tissue and cell establishments developed, implemented and tested 4. Guidance brochure and information leaflet on tissue, cells and organs donation produced	▪ the Audit report submitted to MoH and beneficent within 2 months after project start ▪ 100 employees of tissue and cells establishments and organ transplant centres taking part on the training of QMSG ▪ tissue and cells establishments and organ transplant centres using new developed system by the end of 2007 ▪ HW installed at the Slovak Medical University and functioning by the end of 1st Q 2008 ▪ 1000 copies of brochure and 2000 copies of leaflet issued by the end of the project	▪ Training programmes and performance report ▪ Presence list ▪ Protocol of acceptance for SW ▪ Regular project progress reports ▪ Final report ▪ Monitoring reports debriefed in SMSC ▪ Implementation Status Report	▪ Trained staff will stay on their positions, using the gained knowledge ▪ Institutions involved in the unified info system cooperate and actively use the system
Activities	**Means**		**Assumptions**
1. Elaboration of an Audit analysis of current situation in the field 2. Design and implementation of an unified quality management system guide 1. Elaboration of QMSG 2. Provision of set of specialised trainings 3. Development of a specific software and procurement of equipment for SCOT 3.1 Preparation of the unified information system 3.2 Development of the software 3.3 <u>Procurement of the special equipment for SCOT to ensure the high quality of unified information system</u>	One Twinning contract Service contract Supply contract	0.500 mil Euro 0,350 mil Euro 0,015 mil Euro	▪ Willingness of particular institutions to participate and provide data ▪ Relevant staff available for planned training ▪ Technical facilities available for the training

3.4 Pilot testing 4. Preparation and development of the brochure and the leaflet			

Preconditions
• Qualified Twinning proposals received in time

TIME IMPLEMENTATION CHART

Project title **Improvement of the safety, quality and availability of organs, tissues and cells for transplantation.**

	2006				2007				2008			
Project component	1st Q	2nd Q	3rd Q	4th Q	1st Q	2nd Q	3rd Q	4th Q	1st Q	2nd Q	3rd Q	4th Q
Twinning					**X**	**X**	**X**	**X**				**X**
Audit analysis					**X**	**X**						
QMSG developed and issued						**X**	**X**					
Training of relevant staff							**X**					
Software specification prepared by the working group							**X**	**X**				
TA procurement								X	**X**	**X**		
Software development and installation										**X**	**X**	
Procurement of the special equipmer for SCOT							X	X	X			
Software training of relevant staff											**X**	**X**
Preparation and printing of brochure and leaflet							X					
Pilot testing												X

CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE

Project title **Improvement of the safety, quality and availability of organs, tissues and cells for transplantation.**

MEUR

	2006				2007				2008			
	1.Q	2.Q	3.Q	4.Q	1.Q	2.Q	3.Q	4.Q	1.Q	2.Q	3.Q	4.Q
Contracted					0,500			0,865				
Disbursed					0,300			0,525				0,865

- Request for Modification of Project Fiche

Programme Title	2005 Transition Facility Programme
Project Number	2005/017-464.04.02
Project Title	Improvement of the safety, quality and availability of organs, tissues and cells for transplantation
Sector	Health
Location	Bratislava, Slovak Republic
Total Project Budget	850 000,- Euro
Modified Total Project Budget	865 000,- Euro
Contracting Expiry	15 December 2007
Disbursement Expiry	15 December 2008

A. Justification of the modification

The project is aimed at introduction of quality management for organ transplantation, tissue and cell banking. This purpose should be ensured through the work of the expert team within the twinning component and by means of the Technical Assistance that should develop a new unified information system for transplantation centres, tissue and cell establishments. The information system (IS) will form an integral part of The National Transplant Registry dealing with all necessary information to ensure the safety of transplanted organs, tissues and cells according to national and European law.

The ToR for the software on IS is currently being prepared and the public procurement will be launched most probably in July/August 2007. However, the existing hardware at the Slovak centre for organ transplantation at the Slovak Medical University where the SW will be installed is not sufficient to cover:

- increasing amount of data, as the additional information about tissues and cells will be included and additional information about organs will follow;
- expected increased number of users of the system and higher requirements for the safety, because of the storage of specific and sensitive medical data and the fact that the system will operate through the web.

Therefore, the need to provide complementary technical equipment (e.g. data server, transaction and firewall servers) and secure additional financial resources to cover the costs of the hardware was identified. This issue is highlighted also in the Interim Evaluation Report No. R/SK/TF/ESC/06.003 and the respective recommendation of the evaluators appealing on the Ministry of Health of the Slovak Republic (MoH) and the beneficiaries to minister sustainability of the project's outputs through adequate technical equipment was agreed at the Debriefing meeting held on 27 February 2007.

Based on the above-mentioned facts, additional activity of the project – supply of the specific hardware – is proposed, together with the request for parallel co-financing in the amount of 15,000 Euro. It has to be underlined that the requested change will help to achieve planned results of the project and, moreover, improve the future sustainability of the project outputs. Further financing of

the information system support and services is planned through SCOT budget (provided by the MoH due to the fact that the Slovak centre for organ transplantation was delegated by the MoH to maintain The National Transplant Registry).

Pursuant to the organizational changes at the MoH and the beneficiary institutions (e.g end of employment relationship of previous project leader/SPO Ms. Sklublova with the MoH), certain adjustments have been made in the institutional framework of the project as well as in the implementation schedule, respecting the actual situation.

B. Requested changes in the Project Fiche

- To include the supply of the special equipment[1] under the activity 3.4.3 "Development of a specific software" which will then be changed as follows: 3.4.3. "Development of a specific software and procurement of equipment for Slovak centre for organ transplantation (SCOT) ".

- To increase the budget of the project by 15,000 Euro (parallel co-financing[2] for the supply of the technical equipment).

€M	**Transition Facility support**			**Co-financing[3]**			**Total cost (TF plus cofinancing)**
	Invest-ment Support	Institu-tion Building	**Total Transition Facility (=I+IB)**	National Public Funds	Other Sources	Total co-financing of the project	
Twinning (contract 1)		*0,500*	*0,500*				*0,500*
Technical Assistance (contract 2)		*0,350*	*0,350*				*0,350*
Supply (contract 3)				*0,015*		*0,015*	*0,015*
Total		*0,850*	*0,850*				*0,865*

- To reflect the current situation in the project management and organisation:

The Project leader on the Slovak side will be:
MUDr Richard Raši, MPH
University Hospital Bratislava
Ružinovská 6
826 06 Bratislava
Tel.: +421 2 4823 4645
e-mail: rasi@fnspba.sk
SPO

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[1] The list of the technical equipment (HW) is included as Annex 4 in the modified Project Fiche.

[2] The public procurement (supply of the HW) will be organised and managed by the beneficiary (the Slovak Medical University).

[3] Parallel co-financing

Mr. Edmund Škorvaga
Ministry of Health of the Slovak Republic
Limbova 2
Bratislava 837 52 Slovakia
Tel.: +421 2 59373 308
Fax: +421 2 54776 051
e-mail: edmund.skorvaga@health.gov.sk

PAO:
Ms. Silvia Matúšová
Acting CFCU Director/PAO
Štefanovičova 5
817 82 Bratislava 15
The Slovak Republic
Tel: +421 2 5958 2545
Fax: +421 2 5958 2559
e-mail: silvia.matusova@mfsr.sk

C. Annex

Modified Project Fiche

1.	Does the modification involve a change of the objectives/results of the project as set out in the Phare Financing Memorandum/ Transition Facility Financial Decision?	**no**
2.	Existing project to be suppressed or new one created?	**no**
3.	Is the objective/result of the National Programme/ CBC modified?	**no**

8. If you have answered no to the above questions, the Commission shall be informed in writing. The Commission may raise objection within 10 working days from receipt of the notification. After expiry of that deadline, the Commission is deemed to have given its approval. In this context, the following steps need to be followed:

1. Request by the SPO on ___/___/____ _____
(name) (signature)
_____

2. Approval by the PAO on ___/___/____ _____
(name) (signature)
_____

3. Approval by the NAO on ___/___/____ _____
(name) (signature)
_____

4. Approval by the NAC on ___/___/____ _____
(name) (signature)
_____

Transmission of the modification notification to the European Commission on ___/___/_____