

4 th 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 December 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 Twinning 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

Twining Contract No.	200501746404-0201-0001
Project title	Improvement of the safety, quality and availability of organs, tissues and cells for transplantation
Twining partners	Ministry of Health (IT), in cooperation with the National Transplant Centre (IT) Ministry of Health (SK), University Hospital Ružinov in Bratislava (SK)
Report	4 th Quarterly Report
Period covered by the report	05 September 2007 – 04 December 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.Roosevelt 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 financial resources. The result is a very low rate of donations, which achieves annually less than 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 corrective and preventive action 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 during the period of time herein reported:

Component 2:

- Provision of Medium and Short Term Courses for trainees coming from organ, tissue and cell establishments in Slovakia

Component 4:

- Development of Brochure for donation and transplantation centres in Slovakia as synthetic version of Quality Management System Guide for organs, tissues and cells
- Development of Leaflet for public to support awareness campaign by MoH regarding donation and transplantation in Slovakia
- Preparation of November 2008 Closing Conference and related press conference

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 %
Project Coordination				8	1	12,50%
	GANASSI AGGER Simona	19-20 September 2007			1	
Activity 2.2	Provision of set of specialized trainings			106	44	41,50 %
	FEHILY Deirdre	17-21 September 2007			4	
	PICCOLO Giuseppe	17-21 September 2007			4	
	MIGLIACCIO Giovanni	17-21 September 2007			3,5	

	VALERI Maurizio	17-21 September 2007			4	
	INTRONA Martino	18-20 September 2007			2	
	PORTA Eliana	18-21 September 2007			3	
	PONIATOWSKI Stefan	17-21 September 2007			4	
	FEHILY Deirdre	24-28 September 2007			3	
	PICCOLO Giuseppe	24-28 September 2007			3	
	VALERI Maurizio	24-28 September 2007			3	
	LOMBARDINI Letizia	24-27 September 2007			2,5	
	PIANIGIANI Elisa	24-29 September 2007			3	
	RIDOLFI Lorenza	14-16 October 2007			2	
	PETTINAO Paolo	15-16 October 2007			1	
	ZANELLO Marco	15-16 October 2007			1	
	GIORDANO Francesco	15-16 October 2007			1	
Activity 4.1	Preparation and development of the guidelines brochure			15	6	40,00 %
	BARIANI Fiorenza	12-15 November 2007			2	
	DI CIACCIO Paola	12-15 November 2007			2	

	GENTILE Margherita	12-15 November 2007			2	
Activity 4.2	Preparation of the leaflets and dissemination materials			10	3	30,00 %
	BARIANI Fiorenza	12-15 November 2007			1	
	DI CIACCIO Paola	12-15 November 2007			1	
	GENTILE Margherita	12-15 November 2007			1	

3rd STEERING COMMITTEE MEETING

The third **Steering Committee** was held on September 19th 2007 at MoH in Bratislava. The participants were: RTA Mr. Lauro, RTA-A Ms Kotzigová, PM Mr Koller, SPO Mr Skorvaga, Ms Vallova (MoH),CFCU Mr Škvarka, DPL Ms Agger. The progress of the project during last 3 months (June-July and August 2007) was discussed, together with the 3rd quarterly report.

A plan for the following activities was made and it will be reported in the next paragraphs.

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.

- 2.2 Provision of set of specialized trainings

- 2.2.1 , 2.2.2 , 2.2.3 Short Term Courses and Medium Term Courses:

2.2.1 Original design of **SHORT TERM COURSES**:

These courses were originally 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 **SHORT TERM COURSES**:

During a meeting in Bratislava at the end of March between the RTA Mr Lauro, the DPM Mr Kuba and the STE Mr Ghirardini it was stated by DPM 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 activity to the twinning contract - some Site Visits on Slovak coordination centres located in Bratislava, Martin, Banska Bystrica and Kosice, made by Italian STEs, 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 Mr Nanni Costa and were fully approved by him.

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 (MoH) about all these new activities. The Slovak PL approved all these site visits to coordination centres and SCOT as well as the new Italian STEs Ms Ridolfi and Ms Peritore.

– Re-designing **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 has foreseen a first day dedicated to an “interactive course”, with Italian and Slovak “teachers” together performing “role playing” meetings inside small groups of trainees : they were supposed to discuss with Slovak coordinators and anesthesiologists how to better organize the network of donations and transplantations in Slovakia. Slovak coordinators and anesthesiologists were supposed to interact with Italian STE and DPM Mr Kuba (responsible for SCOT-Bratislava) in order to actively discuss the way of improving the network between coordination centres and designing a common “organizational model” of a coordination centre. A second day was more conventionally dedicated by STEs to some mentions on 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 was to postpone this course after the deadline of August 31st 2007, into the autumn time (October 2007).

- Development of **SHORT TERM COURSES:**

The Short Term Course was held on October 15th and 16th , 2007 at Ruzinov hospital in Bratislava.

The programme, list of participants and Ms Ridolfi's comments (agreed with Mr Kuba) related to this course are enclosed in this report as **Annex 1**, while slide presentations are enclosed as a **CD**.

The course was coordinated by Italian STE Ms Ridolfi.

MoH sent an official letter of invitation to the head-coordinators of 4 coordination centres in Slovakia.

RTA and RTA-A sent an official invitation by email as well, while later the twinning team contacted personally by emails and phone calls all the potential participants (the list of contacted persons is included in Annex 1).

The course was attended by 14 participants (coordinators and anesthesiologists) coming from different areas of Slovakia.

During the course, the lectures were given by 4 Italian STEs (Ms Ridolfi, Mr Zanello, Mr Pettinao and Mr Giordano), by Mr Kuba (as responsible of SCOT-Bratislava) and by 3 Slovak coordinators coming from Bratislava (Mr Krsek) , Martin (Mr Miklusica) and Kosice (Mr Hudak) area. Mr Nanni Costa could not attend the course and he was replaced by Ms Ridolfi. Also Mr Sykora (coordinator from Banska Bystrica area) was not able to attend the meeting, but Banska Bystrica Coordination Centre sent two trainees anyhow.

The first day was dedicated to compare the two different regional and national coordination systems between Slovakia and Italy - followed by a round table on this topic, while the second day was dedicated to an active discussion on donation process and related clinical cases. Moreover the results so far achieved through the TW project were reported by RTA.

Simultaneous translation was available and the slides were projected in Slovak language.

MoH supported financially the CME credits (SACCME credits) for the participants and the refreshments.

In the *Assessment section*, there will be added some technical comments to this course.

2.2.2 , 2.2.3 MEDIUM TERM COURSES:

Generally MEDIUM TERM COURSES were dedicated as per TW contract to transplant centre trainees in order to teach them how to apply and use on a daily working basis the QMSGuide, developed in the previous phase of the project by Italian and Slovak STEs in order to foster in Slovakia the EU Directives regarding transplantation.

2.2.2 Designing MEDIUM TERM COURSES addressed to tissue establishments:

Such courses were 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 May monthly meeting by RTA 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 still are no precise EU directives on QMSGuide for organs.

- Development of MEDIUM TERM COURSES

These specific trainings provided an explanation of the specific parts of the QMSGuide according to each group's specialization. Trainings were foreseen inside the contract for about 50 health care personnel and 50 staff of tissue and cells establishments and organ transplantation centers. They were foreseen as 8 days courses at Ruzinov hospital in Bratislava.

During the monthly meeting held in May, an extra financial support for the medium term courses was asked by RTA to SPO Mr Skorvaga, as inside the TW Project a financial support for travel and accomodation expenses of the Slovak trainees was not clearly foreseen.

The MoH did NOT add an extra-financial support to these courses (as per MoH statement, reported by Mr Skorvaga during the following July monthly meeting).

The Italian CNT-Roma (Italian National Transplant Centre) decided indeed to support these courses, affording the expenses of CME credits (SACCME credits) for participants and refreshments during the courses.

Medium term courses (MTC) 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 an increased attendance of Slovak trainees. This decision was communicated by RTA to MoH (Mr Skorvaga) during May monthly meeting as well.

The courses were coordinated by Italian STEs Mr Piccolo and Ms Fehily.

The courses were divided in the following way: MTC 1 (18 and 19.09.07), MTC 2 (20 and 21.09.07), MTC 3 (25 and 26.09.07) and MTC 4 (27 and 28.09.07).

The programme related to these courses is enclosed in this report as **Annex 2** and the slide presentations can be found on the **CD**.

MoH sent 2 official letters of invitation to all Directors of transplant centres along Slovakia in order to increase the participation to these courses, while the twinning team was contacting the participants personally by email and phone calls.

The MTCs were attended by 43 participants coming from all along Slovakia.

Only **6 centers** (out of 18- around 33%) **did NOT participate** at all at the MTCourses: 1) Liver Tx Centre in Bratislava, 2) Kidney/Pancreas Tx Centre in Banska Bystrica, 3) Kidney Tx Centre in Kosice, 4) Eye Bank in Banska Bystrica, 5) HPC Bank Oncology Kramare in Bratislava, 6) HPC Bank in Kosice.

Due to the poor number of participants at the last MTC 4 (some of the trainees cancelled their presence at last moment without previous notification), this course lasted only one day: therefore the days spent over the courses were 7 instead of 8.

During the courses, the lectures were given by 8 Italian STEs (Mr Piccolo, Ms Fehily, Mr Valeri, Mr Migliaccio, Mr Introna, Ms Porta, Ms Lombardini and Ms Pianigiani), by PM Mr Koller and DPM Mr Kuba, by 2 Slovak experts (Mr Mistrik and Ms Jarabinska) and by 2 EU experts (Mr Bregeon and Mr Poniatowsky).

The programme has foreseen a first day dedicated to presentation of results of TW project by RTA, presentation of the Slovak legal framework about transplantation, QMSGuide overview about organs, tissues and cells, and discussion of clinical cases with trainees. The second day was dedicated to the EU legal framework regarding transplantation, to donor process and other clinical cases opened to discussion from audience.

Simultaneous translation was available.

During the courses it was clearly explained to all participants the possibility to read the **full version of QMSGuide** by Internet on the MoH web site (since the beginning of October 2007): www.health.gov.sk.

In the *Assessment section*, there will be added some technical comments to these courses.

Activities of Component IV:

Preparation of guidelines, booklet, info and CD, information leaflets and dissemination materials

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

■ 4.1, 4.2 Preparation of guidelines, brochure, leaflets and dissemination materials

4.3 Preparation of Closing Conference

The mission related to this component was held from November 13th to November 15th 2007. Participants met at Ruzinov hospital and they were STEs Ms Di Ciaccio (CNT-Roma), Ms

Bariani (CNT-Roma), Ms Gentile (CNT-Roma), plus RTA, RTA-A, PM Prof Koller and DPM Dr Kuba. Furthermore a meeting was held at MoH between STEs, RTA , RTA-A and SPO Mr Skorvaga together with Ms Vallova (MoH) in order to discuss the mission's results and to plan further activities. They worked on : 1) Production of 1500 copies of a color Brochure as synthetic version of QMSGuide, with an annexed CD containing the full QMSGuide plus relevant Slovak legislation. It will be edited in English and Slovak language and will be distributed by MoH and SCOT to ICUs involved in procurement, dialysis centers, transplantation and coordination centres (through Directors and Responsible persons); 2) Production of 5000 copies of a color Leaflet for public, written as a draft in English language and later translated into Slovak language for public dissemination, in order to support an awareness campaign towards donation and transplantation in Slovakia by MoH. It will be distributed through MoH and SCOT.

3) Preparation of the 2008 Final Conference (especially regarding the related national Press Conference), to be held **at MoH on November 5th 2008** (to be confirmed). The relevance of the conference should be at a national and international level.

Activity 4.1 consisted 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 and related EU Directives. The CD annexed to the brochure will report the relevant Slovak legislation and the full QMSGuide and it 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), and will be produced in color version and 1500 copies. The languages for brochures and guidelines are Slovak and English.

The leaflet will be prepared by the STEs in a color version and 5000 copies will be printed within the project budget. It will be directed to public, written in English language and later translated into Slovak language for public dissemination, in order to support an awareness campaign towards donation and transplantation in Slovakia by MoH.

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 regarding the organ donation and transplantation.

The dissemination materials will be prepared taking into consideration that a possible subsequent public awareness campaign will be launched by competent Slovak 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 in Slovakia. Particular attention will also be devoted to organ donation, taking into account Slovak legislation in this specific field.

The **drafts** of the Brochure and Leaflet, developed during Component IV but to be completed in some parts, are enclosed as **Annex 3**.

For the printing company, a marketing research must be done in compliance with the legislation on the Public procurement.

4th STEERING COMMITTEE MEETING

On November 22nd, 2007 the 4th Steering Committee Meeting was held at MoH. The participants were: RTA Mr Lauro, RTA -A Ms Kotzigova, SPO Mr Skorvaga, Ms Vallova (MoH), IT PL Mr Nanni Costa, PM Mr Koller, DPM Mr Kuba, CFCU representative Mr Skvarka.

The progress of the TWproject and the plan for 2008 was discussed as well as the 4th quarterly report.

Timing & Delays

Adherence to schedule

In the fourth quarter, there have been implemented the activities of Component 2 and 4 according to the schedule of the twinning work-plan. A minor change in **Component 3** was foreseen (as previously reported in 3rd quarterly report) due to other missions planned after the software-tender: whenever the IT company will be ready to start to work on software development (by December 2007 as per TW contract), DPM Mr Kuba from Slovak side and STEs Mr Ghirardini and Ms Scaglia from Italian side will take action in order to drive the IT company in its work. Other missions of Italian STE in Bratislava -regarding software development- will be agreed between STE themselves and DPM Mr Kuba in 2008: this topic was fully debated by RTA with SPO Mr Skorvaga at October monthly meeting.

About activity 4.1 and 4.2 of Component IV, the draft of Brochure and Leaflet was developed within the project frame: after printing, the dissemination activity will be held during 2008 as per contract.

Project Month		5	6	7	8	9	10	11	12	13	
Component 3. Development of a specific software											
3.1 preparation of the unified information system											



Expected to be delayed

Recuperation of delays

Regarding Component 3, **activity 3.1** (Preparation of Unified Information System) will foresee other missions after the tender (month 13) for the reasons explained above while **activity 3.2** (public procurement for Slovak IT company plus beginning of activity of Slovak IT company) is foreseen in adherence with TW project time frame, as well as **activity 3.3** (pilot testing, due between August and November 2008).

Development of **activity 4.3** (closing conference and connected dissemination of material) is foreseen in adherence with time schedule.

ASSESSMENT

Overall assessment of progress

The Audits performed last February 07 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.

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 fostered by transplant centers. Furthermore, every Guide needs to be read and applied on the field: this was the reason to run Medium Term courses inside the twinning project, in order to foster the conformity with the EU Directives reported inside the QMSGuide for Slovakia.

Regarding Short Term Courses, they were foreseen inside the project in order to update the training of coordinators and anesthesiologists among Slovakia: Site Visits by STEs were useful in order to plan such a course - appropriated to Slovak coordination centres and SCOT's reality.

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 - was the main reason to develop a new specific software. Through few missions, STEs could get a clear picture of the real situation of the old software at SCOT in Bratislava 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. As previously reported, new missions of STEs will be necessary when the IT Company will be ready to start, in order to make a common plan of action.

Component IV was implemented in order to “advertise” the project among centres in Slovakia but with the ultimate aim to give tools to them and MoH to increase public awareness towards donation in Slovakia, increasing consequently transplantation.

Activities and goals achieved during the reported framework : *Component IV and Component II*

Component IV was developed during November 2007, in order to achieve its real goal in 2008: to spread the project out among Slovak coordination and transplantation centres, as well as to increase public awareness towards donation implementing, consequently, transplantation. This last issue will be deepened in the „issue arisen“ section.

The main goal of Component II was only partially achieved, due to the lack of participation of few centres to the courses: anyhow the majority of centres (around 66%) participated and learned how to handle and use on a daily working basis the QMSGuide and consequently to foster the EU directives regarding tissue and cell transplantation and EU suggestions regarding organs.

This topic, and the need of MoH 2008 Audits (monitoring) in order to verify the application of QMSGuide by centres in Slovakia, will be fully debated inside the „issue arisen“ section as well.

Following activities :

COMPONENT III

Component III (development of a specific software) and its activities 3.2 and 3.3 will be developed starting by December 2007, in close collaboration between Italian STEs Mr Ghirardini and Ms Scaglia and DPM Mr Kuba, responsible for the software at SCOT-Bratislava. The starting activity of IT company will be carried out no later than end of the year (as foreseen in the project). The need for other missions of STEs has already been reported.

Finally the pilot testing (activity 3.3) for the new software will be performed between August and November 2008.

COMPONENT IV

Activity 4.3 (closing conference and connected dissemination of material) will be held by November 2008.

The Final Conference (with the related press conference) will be prepared in order to have a high relevance nationally and internationally and it will be held at MoH on November 5th, 2008 (to be confirmed).

One of the major goals of the conference, in addition to the presentation of the results of the project, will be to focus the attention of the general Slovak public on the issues related to the transplantation of organs and tissues; therefore it should have high relevance nationally and be perceived by the general public also as an important international event.

The methods involved in the organization of a scientific event, as well as the one used for a dissemination event, will be applied.

The persons invited to participate will be selected according to the criteria of institutional representation and public visibility.

Special attention will be given in involving the media both at the national, European and international level.

The conference will last one day and will be followed by a press conference, in which Slovak and Italian authorities, the PLs, RTA and other persons involved in the project, will illustrate to the press the obtained results .

During the conference , the dissemination materials will be presented to the press and distributed.

It was agreed that the Dissemination of informative materials will start at the beginning of 2008 and will follow over the whole year.

Issues arisen

- **Participation at Short and Medium Term Courses**

It is worthwhile to underline that the overall participation to these courses was represented by 57 trainees all together, instead of 100 as foreseen inside the TW contract; moreover, the duration of Medium Term Courses was reduced to 7 days instead of 8 because of poor number of participants to last MTC 4 course.

There are 4 main explanations or remarks to this topic, all of them fully debated and agreed at the October monthly meeting with SPO Mr Skorvaga:

1) **100 participants**, as foreseen inside the original TW contract, were probably too many (average 2-3 participants per centre = around 70 participants maximally, considering all together transplant and coordination centres in Slovakia);

2) the **financial support** was part of the problem but, affording the travel and accomodation expenses of participants by SK MoH (or by Hospitals themselves - as it was stated by MoH), it would have increased the attendance to the courses .

PM Mr Koller as well as the twinning team received many phone calls from transplant centres complaining about this issue;

3) the project was very well advertised during 2007 (RTA trips through centres, Kick off Meeting in Bratislava, Audits by STEs, Audit Conference in Bratislava, Site Visits by STEs, Scientific Meetings where RTA was invited in all main towns among Slovakia) but maybe it was **little advertised in the previous year 2006** - people working inside the centres needed probably more time to „digest“ and get acquainted to such a huge national project and to understand the importance to participate in it;

4) in some centers there are just **few people** actively working, so they probably did not have the opportunity to attend the courses, due to their poor number and amount of daily work.

Last remark is, again, the **lack of sense of „whole national transplant community“** between centres themselves and with national institutions (SCOT, MoH)-as it was stated previously by Italian PL Mr Nanni Costa: this lack could have been contributed to this lower participation as well.

Regarding this last topic, the work done by scientific societies like **Slovak Transplant Society** is foreseen by Twinning team as essential in contribution for the re-building of the whole transplant system in Slovakia.

- **Increased number of donations in Slovakia in year 2007**

The TW project has probably contributed to increase the total number of Slovak donors collected so far (**more than 100 donors** up to date since the beginning of year 2007): in fact, comparing to the same period of year 2006, the number of donors in Slovakia has raised notably (almost doubled), probably as a **“twinning” effect** and because of the **new slovak laws on transplantation** discussed in the previous report.

Remarkably , in 2004 there were **10.2** donations per 1 million of inhabitants in organ transplantation in Slovakia, while in 2007 it was achieved **almost 20** donations per 1 million of inhabitants.

- **Relationships between transplant centres and MoH: the idea of a “transplant community” and the need of financial support to SCOT, coordination and transplant centres**

As already reported, during the Audit Report Conference, held last March 07 at MoH in Bratislava, Italian PL 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. Another option should be to empower SCOT, creating a different institution acting as a National Transplant Centre. This National Transplant Centre in Slovakia 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.

Slovak Transplant Society is working on this topic in collaboration with MoH.

But anyhow, in order to create a “new” SCOT as an institution fully independent and functioning, a financial support will be necessary.

The same need of financial support was claimed by all the transplant and coordination centres, during RTA first trip along Slovakia and during the Audits and Site Visits as well: this issue must be fully considered by SK competent health care authorities.

- **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 **activity 4.2**.

In strict collaboration with PM Mr Koller and DPM Mr Kuba, the twinning team planned meetings with some scientific societies where RTA was invited to present the project, as already reported inside the 2nd and 3rd quarterly report.

Apart from the meetings described inside the previous quarterly reports, RTA was invited (through CNT-Roma) in Coccaglio (**Brescia -Italy**) on 13.10.07, where he presented and discussed the twinning project at the International Conference on “Organ,tissue,cell and blood donation worldwide: comparison between different international experiences”, reporting the progress of the project in Slovakia.

The meeting represented a good opportunity to better explain the steps of the project to an international audience , comparing this experience with different international ones.

Moreover, RTA and IT PL were invited at the **2008 CH-SK Bilateral Transplant Conference**, that it will be run by Czech and Slovak Transplant Societies and held in Slovakia on September 2008 : there will be a specific session dedicated to the results of 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.

On September 07, RTA Mr Lauro spoke with representative of EU Commission Mr Bregeon about the possible agreement between Italy and Slovakia on liver transplantation (as reported inside the previous reports).

On October 31st, 2007 some REMARKS by MoH on the agreement (called by now “Declaration of Intent”) were received by IT PL Mr Nanni Costa: the agreement was written again following the remarks and presented to MoH one week later.

As a consequence, on November 20th, 2007 the IT PL Mr Nanni Costa met Mr Fernandez-Zincke, representative for Organ Transplantation of the **EU Commission – Health and Consumer Protection- Directorate General** in order to talk about this possible agreement between Italy and Slovakia on liver transplantation.

Furthermore, on November 22nd, 2007 Mr Nanni Costa came to Bratislava in order to discuss with MoH representative Ms Liptakova the new **MoH remarks on the 2nd version of Declaration of Intent**.

This possible common project on liver transplantation between Italy and Slovakia was useful to the twinning project for the following reason, even if it is clearly an extra twinning activity, outside the goal of the project.

Marginal donors were taken into account as potential liver donors to be offered abroad, if not used for Slovak cirrhotic patients.

Up to half of November 2007 Italy, through a CNT organization called “Italian Gate to Europe” in Rome, got 12 marginal livers from Slovakia for 12 cirrhotic recipients since “two days visit” of Slovak experts on March 2007 in Italy (previously reported): 3 livers went to Bologna, 5 to Modena, 2 to Ancona, 1 to Torino and 1 to Roma.

All these 12 recipients 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 liver donors collected so far : **37 liver donors** in Slovakia up to **October 07** (only 20 livers in whole 2006, almost doubled) . They were sent to Czech Republic 19 livers, to Italy 12 livers, to Austria 4 and to Germany 2. Regarding the Coordination Centres, Martin harvested 17 livers (10 to Italy-in 2006 Martin harvested only 3 livers), Bratislava 9 (6 to Czech Republic), Banska Bystrica 6 (all to Czech Republic) and Kosice 5 (2 to Italy).

Recommendations

Medium Term courses were attended by the majority of transplant centres but it will be necessary by MoH to verify **through internal MoH 2008 Audits** if QMSGuide (and the EU Directives reported inside) will be apply on the field in 2008 , especially by those centers not participating to the course.

These internal Audits should happen earlier than the Final Conference on November 2008, before advertising and disseminating the results of the project to the public. In fact one of the Benchmarks of the project is that the facilities included in the project will be accredited by the beginning of 2009, fulfilling the requirement of the directive 2004/23/EC.

The **brochure (as a synthetic version of QMSGuide)** will help the knowledge of the EU Directives by centers as well as the internet publication **on MoH web site of the QMSGuide** will reinforce it .

The **leaflet** will support the public campaign, held by MoH, towards donation and transplantation in Slovakia.

The **Final Conference** will raise the donation and transplantation issue in Slovakia to a national and international level.

The topic of **Short Term courses** will necessitate to be repeated from time to time, as it has already been designed and organized by local slovak committee of ETCO in 2005 and 2007.

The old **software** needed to be updated and it will be realized by the project, taking into account that also a hardware should be necessary in order to fully support the SW.

SCOT needs to be empowered as a **new National Tranplant Center** , as well as the network between coordination and transplant centres, realizing a real "**transplant community**", interacting scientifically and medically between themselves and with MoH.

Financial support needs to be foreseen in next years to fully support the „new SCOT“ and this transplant community: the work of **Slovak Transplant Society** in this direction is foreseen as essential step to create a new national transplant programme.

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**: the mortality rate of cirrhotic patients in Slovakia is still triple compared to other EU countries and this must be addressed and corrected by MoH through appropriate action. The presence of a own liver transplantation programme will increase **organ donation in Slovakia** as well.

EXPENDITURE TABLE

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. 4 and 5	Amount charged to contingencies
1	Resident Twinning Adviser Augusto Lauro (13 months)										
	Basic salary	September, October and November 2007	salary slips		Gross salary			€ 9.075,10	€ 71.604,26		
	Non-wage labour costs (36,031 %)							€ 3.568,48	€ 25.799,73		
	6% of salary and non-wage labour costs							€ 758,61	€ 5.844,24		
	Total RTA remuneration							€ 13.402,19	€ 103.248,23		
2	Resident Twinning Advisor Allowances										
	Daily Allowances (50%) 13 months	September, October and November 2007	salary slips		September = 19 per diem October = 18 per diem November = 23 per diem			€ 5.250,00	€ 34.562,50		
	Allowances for RTA for first 30 days								€ 5.250,00		
	Health and accident insurance for RTA								€ 2.600,00		
	Accommodation	20 August - November 2007	apartment rent receipts	20 August 20 September 20 October 2007				€ 2.100,00	€ 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	September, October and November 2007	RTA statements use of car		September = 325 € adjusted to days worked October = 375 € adjusted to days worked November = 425 € adjusted to days worked			€ 1.125,00	€ 6.050,00		
	Total RTA Allowances							€ 8.475,00	€ 62.437,50		
6	Project Co-ordination/Management Costs										
	Participation of PL/DPL in PSC meetings							€ 500,00	€ 2.000,00		
	'Project Management Costs'							€ 750,00	€ 3.000,00		
	Per diems							€ 175,00	€ 2.100,00		€ 30,00
	International travel							€ 947,71	€ 2.800,00		€ 202,41
	Visibility costs[1]								€ 2.000,00		
	Audit certificate costs[2]								€ 4.000,00		
	Total Project Co-ordination/Management Costs							€ 2.372,71	€ 15.900,00		€ 232,41
	1st Mission of GANASSI AGGER Simona	19-20/ September/ 2007	MC n. 7/IV		Arrival 19.09.2007 Roma / Vien 10.35 / 12.25 flight n. AP 1506 Departure 20.09.2007 Vien / Rome 07.30 / 09.10 flight n. AP 1505						
	Fees				1 x 250			€ 250,00			
	'Project Management Costs'				1,5 x (1 x 250)			€ 375,00			
	Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December			€ 175,00			€ 30,00
	Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04. Statement use of car	September 2007 23 October 2007	Economy Class Rome / Vienna / Rome: € 214,71 Use of car from Vienna Airport to Bratislava and return: (Km 66 * 0,25)*2= € 33,00						
	<i>Sub Total</i>							€ 247,71			
								€ 1.047,71			
	Mission of PL Nanni Costa	22 November 2007	MC n. 21/IV		Arrival 22/11/2007 Bologna/Vien 8:00/9:30 flight n. OS 0536 Departure 22/11/2007 Vien/Bologna 17:45/19:25 flight n. OS 0549						
	Fees				1 x 250			€ 250,00			
	'Project Management Costs'				1,5 x (1 x 250)			€ 375,00			
	Per diem										
	Air ticket		Flight ticket Statement use of car	03 December 2007	Business Class Bologna / Vien / Bologna: € 869,41 was cheaper than the economy class as confirmed by the relevant statement issued by Travel Agency Orsa Maggiore Use of car in date 21 Vien airport to Bratislava						€ 202,41
	<i>Sub Total</i>							€ 700,00			€ 202,41
								€ 1.325,00			€ 202,41

7 PROJECT ACTIVITIES										
Component 1: elaboration of an audit analysis of the current situation in the field										
Activity no. 1.3 Audit										
Expert fees								€ 12.250,00		
'Project Management Costs'								€ 18.375,00		
Per diems (3)								€ 12.250,00		
International travel								€ 4.900,00		
local travel								€ 2.750,00		
RTA and RTA-A local travel								€ 1.700,00		
RTA per diem for missions outside Bratislava								€ 700,00		
Translation							€ 720,00	€ 2.000,00		
Translation Andrej Klapica		Mr. Klapica debit note	November 2007	Translations of 36 pages of documents regarding the Slovak Laws and the Protocol for donation. Not invoiced and reported in the previous reports			€ 720,00			
Total Activity no. 1.3							€ 720,00	€ 54.925,00		
Activity no. 1.4 Reports and networking activities										
Expert fees 3 MS experts, 3 days each								€ 2.250,00		
'Project Management Costs'								€ 3.375,00		
Per diems (3)								€ 2.100,00		
International travel								€ 2.100,00		
local travel								€ 500,00		
RTA local travel								€ 400,00		
RTA per diem for missions outside Bratislava								€ 350,00		
Total Activity no. 1.4							€ -	€ 11.075,00	€ -	
COMPONENT 2 "design and implementation of a unified quality management system"										
Activity no. 2.1 elaboration of QMSG										
Expert fees 3 Member State exp., 5 days each								€ 2.750,00		
'Project Management Costs'								€ 4.125,00		
Per diems (3)								€ 2.275,00		
International travel								€ 3.544,64		
Translation							€ 1.720,00	€ 2.800,00	€ 2.400,00	
Translation Andrej Klapica	September-October 2007	Mr. Klapica debit note	November 2007	Translations of 86 pages of documents for QMSG			€ 1.720,00			
Total Activity no. 2.1							€ 1.720,00	€ 15.494,64	€ 2.400,00	
Activity no. 2.2 provision of set of specialized trainings										
6 MS Experts Expert fees Short term Training, 3 days							€ 1.250,00	€ 4.500,00	€ 500,00	
11 Expert, 2 x Medium Term Training, 2x4 days each							€ 9.750,00	€ 22.000,00	€ 500,00	
'Project Management Costs'							€ 16.500,00	€ 39.750,00		
Per diems (3)							€ 8.750,00	€ 22.400,00	€ 1.500,00	
International travel							€ 6.970,19	€ 19.600,00	€ 151,01	
Local travel							€ -	€ 500,00		
Translation							€ 1.100,00	€ 3.400,00		
Printing							€ -	€ 2.000,00		
Interpretation simultaneous							€ 3.600,00	€ 3.600,00	€ 2.800,00	
Hiring interpretation equipment							€ 2.336,00		€ 4.160,00	
Total Activity no. 2.2 (see below for details)							€ 50.256,19	€ 117.750,00	€ 6.960,00	€ 1.651,01
6th Mission of FEHILY Deirdre	17-21/ September/ 2007	MC n. 1/IV		Arrival 17/09/2007 Milan/Vien 20:25/12:55 flight n. AZ 196 Departure 21/09/2007 Viena/Milan 18:00/19:20 flight n. AZ 197						
Fees				4 x 250			€ 1.000,00			
'Project Management Costs'				1,5 x (4 x 250)			€ 1.500,00			
Per diem				4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December			€ 700,00		€ 120,00	
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Milan / Viena / Milan: € 337,34 Train from Como Camerlata to Milano Malpensa airport, to take the flight departing from Milano Malpensa in date 17 september 2007 : € 8,10 Use of car in date 21 September 2007 from Milano Malpensa Airport to Como, paid as 1st class ticket of train and bus: € 45,00			€ 360,44			
Sub Total							€ 3.560,44			

6th Mission of PICCOLO Giuseppe	17-21/ September/ 2007	MC n. 2/IV		Arrival 17/09/2007 Milan/Vien 20:25/12:55 flight n. AZ 196 Departure 21/09/2007 Vien/Milan 18:00/19:20 flight n. AZ 197					
Fees				4 x 250				€ 1.000,00	
'Project Management Costs'				1,5 x (4 x 250)				€ 1.500,00	
Per diem				4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December				€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04. Statement use of car	September 2007 20 nov 2007	Economy Class Milan / Vien / Milan: € 337,34 Trip by car from Vienna Airport to Bratislava and return : € 16,50 * 2 = € 33,00 (trip shared with Ms Fehily)				€ 370,34	
<i>Sub Total</i>								€ 3.570,34	
5th Mission of MIGLIACCIO Giovanni	17-21/ September/ 2007	MC n. 3/IV		Arrival 17/09/2007 Rome / Bratislava 15:30 / 17:10 flight n. NE 387 Departure 21/09/2007 Bratislava / Rome 15:05 / 14:45 flight n. NE 386					
Fees				3,5 x 250				€ 875,00	
'Project Management Costs'				1,5 x (3,5 x 250)				€ 1.312,50	
Per diem				4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December				€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Rome / Bratislava / Rome: € 280,95				€ 280,95	
<i>Sub Total</i>								€ 3.768,45	
1st Mission of VALERI Maurizio	17-21/ September/ 2007	MC n. 4/IV		Arrival 17/09/2007 Rome / Bratislava 15:30 / 17:10 flight n. NE 387 Departure 21/09/2007 Vien / Rome 17:30 / 19:10 flight n. AP 1503					
Fees				4 x 250				€ 1.000,00	
'Project Management Costs'				1,5 x (4 x 250)				€ 1.500,00	
Per diem				4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December				€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Rome / Bratislava Vienna / Rome: € 427,64				€ 427,64	
<i>Sub Total</i>								€ 3.627,64	
1st Mission of INTRONA Martino	18-20/ September/ 2007	MC n. 5/IV		Arrival 18/09/2007 Milan-Orio / Bratislava 17:05 / 18:25 flight n. FR4642 Departure 20/09/2007 Bratislava / Milan-Orio 18:35 / 19:55 flight n. FR4643					
Fees				2 x 250				€ 500,00	
'Project Management Costs'				1,5 x (2 x 250)				€ 750,00	
Per diem				2 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December				€ 350,00	€ 60,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Milan-Orio / Bratislava / Milan-Orio : € 415,18				€ 415,18	
<i>Sub Total</i>								€ 2.015,18	
2nd Mission of PORTA Eliana	18-21/ September/ 2007	MC n. 6/IV		Arrival 18/09/2007 Milan / Vien 17:35 / 19:05 flight n. OS 514 Departure 21/09/2007 Vien / Milan flight n. OS 517					
Fees				3 x 250				€ 750,00	
'Project Management Costs'				1,5 x (3 x 250)				€ 1.125,00	
Per diem				3 x 205 € of which 90 € are charged to the contingencies following the change from the 18th of December				€ 525,00	€ 90,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04. Statement use of car	September 2007 16 october 2007	Economy Class Milan / Vienna / Milan: € 262,34 Train and bus from Morgex (AO) to Milano Malpensa airport, to take the flight departing from Milano Malpensa in date 18 september 2007: € 24,80 Use of car in date 21 September 2007 from Milano Malpensa Airport to Morgex (AO): € 52,25. The use of car for the return trip was necessary because of lack of public transports at Spn. Trip by bus to reach Bratislava from Vien Airport: € 10,00 = € 9,00 + € 1,00.				€ 369,39	
<i>Sub Total</i>								€ 2.769,39	
1st Mission of PONIATOWSKI Stefan	17-21/ September/ 2007	MC n. 8/IV		Arrival 17/09/2007 London / Bratislava 19:00 / 22:10 flight n. NA127 Departure 21/09/2007 Bratislava / London 17:40 / 19:00 flight n. NA126					
Fees				4 x 250				€ 1.000,00	
'Project Management Costs'				1,5 x (4 x 250)				€ 1.500,00	
Per diem				4x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December				€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class London / Bratislava London: € 300,00				€ 300,00	
<i>Sub Total</i>								€ 3.500,00	

7th Mission of FEHLY Deirdre	24-28/ September/ 2007	MC n. 9/IV		Arrival 24.09.2007 Milan / Vien 20.25 / 21.55 flight n. AZ 156 Departure 28.09.2007 Vien / Milan 07.20 / 8.50 flight n. AZ 156					
Fees								€ 750,00	
'Project Management Costs'								€ 1.125,00	
Per diem					4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December			€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Milan / Vien / Milan: € 640,34	2.600,00 SKK	1 € = 33,7400 SKK		€ 733,60	
		Train ticket	24 sept 2007 28 sept 2007	Train from Como Camerlata to Milano Malpensa airport and return: 16,20 €					
		Taxi receipt	28 sept 2007	Use of taxi from Bratislava to take the flight departing from Vienna Airport at 7.20 a.m. € 77,05 (= 2.600,00 SKK, according to the InfoEuro exchange rate of September 2007)				€ 3.368,60	
Sub Total								€ 733,60	€ 33,60
7th Mission of PICCOLO Giuseppe	24-26/ September/ 2007	MC n. 10/IV		Arrival 24.09.2007 Milan / Vien 20.25 / 21.55 flight n. AZ 156 Departure 28.09.2007 Vien / Milan 07.20 / 8.50 flight n. AZ 156					
Fees								€ 750,00	
'Project Management Costs'								€ 1.125,00	
Per diem					4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December			€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Milan / Vien / Milan: € 640,34				€ 656,84	
		Statement use of car	20 nov 2007	Trip by car from Vienna Airport to Bratislava: € 16,50 (trip shared with Ms Felby)				€ 3.291,84	
Sub Total								€ 656,84	
2nd Mission of VALERI Maurizio	24-26/ September/ 2007	MC n. 11/IV		Arrival 24.09.2007 Rome / Bratislava 15.30 / 17.10 flight n. NE 387 Departure 28/09/2007 Bratislava / Rome 13.05 / 14.45 flight n. NE 386					
Fees								€ 750,00	
'Project Management Costs'								€ 1.125,00	
Per diem					4 x 205 € of which 120 € are charged to the contingencies following the change from the 18th of December			€ 700,00	€ 120,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Rome / Bratislava / Rome: € 300,35				€ 300,35	
Sub Total								€ 3.275,35	
1st Mission of LOMBARDINI Letizia	24-27/ September/ 2007	MC n. 12/IV		Arrival 24.09.2007 Rome / Bratislava 15.30 / 17.10 flight n. NE 387 Departure 27.09.2007 Bratislava / Rome 13.05 / 14.45 flight n. NE 386					
Fees								€ 750,00	
'Project Management Costs'								€ 937,50	
Per diem					3 x 205 € of which 75 € are charged to the contingencies following the change from the 18th of December			€ 525,00	€ 90,00
Air ticket		Travel Agency Cisalpina Invoice n. 0033750 and 0022963/04.	September 2007	Economy Class Rome / Bratislava / Rome: € 372,35				€ 471,15	
Sub Total		Train tickets		Train from Florence to Rome and return: € 98,8				€ 2.558,65	
1st Mission of PIANIGIANI Elia	24-29/ September/ 2007	MC n. 13/IV		Arrival 24.09.2007 Rome / Bratislava 15.30 / 17.10 flight n. NE387 Departure 29.09.2007 Bratislava / Rome 13.05 / 14.45 flight n. NE 386					
Fees								€ 750,00	
'Project Management Costs'								€ 1.125,00	
Per diem					5 x 205 € of which 150 € are charged to the contingencies following the change from the 18th of December			€ 875,00	€ 160,00
Air ticket		Skyeurope airlines e-ticket receipt	27 July 2007	Economy Class Rome / Bratislava / Rome: € 95,05				€ 215,05	
Sub Total		Statement use of car	02 October 2007	Trip by car from Siena to Rome and return, paid as 1st class train ticket: €				€ 2.958,05	
3rd Mission of RIDOLFI Lorenza	14-16/ October/ 2007	MC n. 14/IV		Arrival 14/10/2007 Bologna / Praga 14.15/15.25 flight n. OK 0731 Praga / Bratislava 17.05/18.05 flight n. OK 0856 Departure 15/10/2007 Vien / Roma 17.30/18.10 flight n. OS 0503					
Fees								€ 500,00	
'Project Management Costs'								€ 750,00	
Per diem					2 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December			€ 350,00	€ 60,00
Air ticket		Travel Agency Cisalpina Invoice n. 0038887 and 0025848/04.	31 oct 2007	Economy Class Rome / Praga / Bratislava Vien / Rome: € 468,61				€ 468,61	
Sub Total								€ 2.668,61	
1st Mission of PETTINAO Paolo	15-16/ October/ 2007	MC n. 15/IV		Arrival 15/10/2007 Cagliari/Roma 7.40 / 8.50 flight n. IG 1781 Roma / Vien 10.35/12.25 flight n. OS 0506 Departure 16/10/2007 Vien / Roma 17.30/18.10 flight n. OS 0503 Roma / Vien 20.30/21.25 flight n. AF 5596					
Fees								€ 250,00	
'Project Management Costs'								€ 375,00	
Per diem					1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December			€ 175,00	€ 30,00
Air ticket		Travel Agency Cisalpina Invoice n. 0038887 and 0025848/04.	31 oct 2007	Economy Class Cagliari / Rome / Vien Vien / Rome / Cagliari: € 470,90				€ 470,90	
Sub Total		Bus Receipt	15 oct 2007	Trip by bus from Vien Airport to Bratislava: € 9,00				€ 1.270,90	

1st Mission of ZANNELLO Marco	15-16/ October/ 2007	MC n. 16/IV		Arrival 15/10/2007 Bologna / Vien 10,55/12,35 flight n. OS 0548 Departure 16/10/2007 Vien / Bologna 17,50/19,35 flight n. OS 0549						
Fees				1 x 250				€ 250,00		
'Project Management Costs'				1,5 x (1 x 250)				€ 375,00		
Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December				€ 175,00		€ 30,00
Air ticket		Travel Agency Cisalpina Invoice n. 0038887 and 0025848/04.	31 oct 2007	Economy Class Bologna / Vien Vien / Bologna: € 817,41				€ 817,41		€ 117,41
<i>Sub Total</i>								€ 1.617,41		
1st Mission of GIORDANO Francesco	15-16/ October/ 2007	MC n. 17/IV		Arrival 15/10/2007 Udine / Bratislava trip by private car Departure 16/10/2007 Bratislava / Udine trip by private car						
Fees				1 x 250				€ 250,00		
'Project Management Costs'				1,5 x (1 x 250)				€ 375,00		
Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December				€ 175,00		€ 30,00
Air ticket		Statement use of car	10 nov 2007	Trip by car from Udine to bratislava and return, paid as 1st class train ticket : € 312,34.				€ 312,34		
<i>Sub Total</i>								€ 1.112,34		
Interpretation simultaneous	18-21 september 2007; 25-27 september 2007; 15-16 october 2007;	Eurokomp Invoice n° 2007 - SK - 110 and invoice n° 2007 - SK - 110	01 oct 2007; 21 oct 2007.	Interpretation during the training activities held on 18-21 september 2007, 25-27 september 2007 and 15-16 october 2007				€ 3.600,00		
Hiring interpretation equipment	18-21 september 2007; 25-27 september 2007; 15-16 october 2007;	Eurokomp Invoice n° 2007 - SK - 110 and invoice n° 2007 - SK - 110	01 oct 2007; 21 oct 2007.	Hiring of Interpretation equipment during the training activities held on 18-21 september 2007, 25-27 september 2007 and 15-16 october 2007				€ 2.336,00		
Translation Andrej Klapica	September 2007	Mr. Klapica debit note	November 2007	Translations of 55 pages of documents for MTC and STC				€ 1.100,00		
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								€ 3.250,00		
'Project Management Costs'								€ 4.875,00		
Per diems (3)								€ 3.150,00		
International travels								€ 1.400,00	€ 700,00	
Translation								€ 240,00	€ 1.000,00	
Translation Andrej Klapica	September 2007	Mr. Klapica debit note	November 2007	Translations of 12 pages of documents for the tender for the software				€ 240,00		
Total Activity no. 3.1								€ 240,00	€ 13.675,00	€ 700,00

COMPONENT 4 Preparation of Guidelines, brochure and information leaflets										
Activity no. 4.1 preparation and development of the guidelines brochure										
3 MS Expert for 5 days each								€ 1.500,00	€ 3.750,00	
Expert fees								€ 2.250,00	€ 5.625,00	
'Project Management Costs'								€ 1.050,00	€ 3.150,00	€ 180,00
Per diems (3)								€ 1.091,13	€ 2.100,00	€ -
International travel								€ -	€ 1.500,00	
Printing/CD or DVD production								€ -	€ 2.500,00	
Translation								€ -	€ 2.500,00	
Proofreading								€ -	€ 2.500,00	
Total Activity 4.1 (details as below)								€ 5.891,13	€ 21.125,00	€ 180,00
5th Mission of BARIANI Firenza	12-15/ novembre/ 2007	MC n. 18/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503						
Fees				2 x 250				€ 500,00		
'Project Management Costs'				1,5 x (2 x 250)				€ 750,00		
Per diem				2 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December				€ 350,00		€ 60,00
Air ticket		Travel Agency Cisalpin Invoice n. 1241042	02 nov 2007	Economy Class Roma / Vien Vien / Roma: € 482,71						
		Statement use of car	20 nov 2007	Trip by car from Vienna Airport to reach Bratislava: € 16,50 (trip shared with Ms Di Ciaccio and Ms Gentile)				€ 499,21		
<i>Sub Total</i>								€ 2.099,21		
1st Mission of DI CACCIO Paola	12-15/ novembre/ 2007	MC n. 19/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503						
Fees				2 x 250				€ 500,00		
'Project Management Costs'				1,5 x (2 x 250)				€ 750,00		
Per diem				2 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December				€ 350,00		€ 60,00
Air ticket		Travel Agency Cisalpin Invoice n. 0038887 and 0025848/04	31 oct 2007	Economy Class Roma / Vien Vien / Roma: € 287,71						
		Statement use of car	20 nov 2007	Trip by car from Bratislava to reach Vienna Airport : € 16,50 (trip shared with Ms Di Ciaccio and Ms Gentile)				€ 304,21		
<i>Sub Total</i>								€ 1.904,21		
1st Mission of GENTILE Margherita	12-15/ novembre/ 2007	MC n. 20/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503						
Fees				2 x 250				€ 500,00		
'Project Management Costs'				1,5 x (2 x 250)				€ 750,00		
Per diem				2 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December				€ 350,00		€ 60,00
Air ticket		Travel Agency Cisalpin Invoice n. 0038887 and 0025848/04	31 oct 2007	Economy Class Roma / Vien Vien / Roma: € 287,71						
								€ 287,71		
<i>Sub Total</i>								€ 1.887,71		
Activity no. 4.2 preparation of the leaflets and dissemination materials										
2 MS Expert for 5 days each								€ 750,00	€ 2.500,00	
Expert fees								€ 1.125,00	€ 3.750,00	
'Project Management Costs'								€ 525,00	€ 2.100,00	€ 90,00
Per diems (3)								€ -	€ 1.400,00	
International travel								€ -	€ 3.000,00	
Printing								€ -	€ 2.500,00	
Translation								€ -	€ 2.500,00	
Proofreading								€ -	€ 2.500,00	
Total Activity 4.2								€ 2.400,00	€ 17.750,00	€ 90,00

5th Mission of BARIANI Fiorenza	12-15/ novembre/ 2007	MC n. 18/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503											
Fees				1 x 250				€	250,00						
'Project Management Costs'				1,5 x (1 x 250)				€	375,00						
Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December				€	175,00	€ 30,00					
Air ticket		Travel Agency Cisalpina Invoice n. 1241042	02 nov 2007	charged on act. 4.1.											
<i>Sub Total</i>								€	800,00						
1st Mission of DI CIACCIO Paola	12-15/ novembre/ 2007	MC n. 19/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503											
Fees				1 x 250				€	250,00						
'Project Management Costs'				1,5 x (1 x 250)				€	375,00						
Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December				€	175,00	€ 30,00					
Air ticket		Travel Agency Cisalpina Invoice n. 0038887 and 0025848/04	31 oct 2007	charged on act. 4.1.											
<i>Sub Total</i>								€	800,00						
1st Mission of GENTILE Margherita	12-15/ novembre/ 2007	MC n. 20/IV		Arrival 12/11/2007 Roma / Vien 17,45 / 19,25 flight n. OS 7004 Departure 15/11/2007 Vien / Rome, 17,30 / 19,15 flight n. OS 503											
Fees				1 x 250				€	250,00						
'Project Management Costs'				1,5 x (1 x 250)				€	375,00						
Per diem				1 x 205 € of which 30 € are charged to the contingencies following the change from the 18th of December				€	175,00	€ 30,00					
Air ticket		Travel Agency Cisalpina Invoice n. 0038887 and 0025848/04	31 oct 2007	charged on act. 4.1.											
<i>Sub Total</i>								€	800,00						
Activity no. 4.3 final conference and connected diffusion activities															
PL-DPL 2 days each and 2 MS									€	2.000,00					
Expert for 2 days each									€	3.000,00					
Expert fees									€	2.100,00					
'Project Management Costs'									€	2.800,00					
Per diems (3)									€	300,00					
International travel									€	10.200,00					
Interpretation simultaneous									€						
Total Activity 4.3								€	10.200,00						
Surplus status line after SL 3									€	1.286,32					
OVERALL TOTAL WITHOUT ASSISTANT AND CONTINGENCIES								€	85.477,23	€	462.689,41	€	10.060,00	€	2.153,42
									19% €	87.630,65					

ANNEX 1

- **PROGRAMME OF STCourse**

**Short-term Course for Professionals working
in Organ Procurement for transplantation**

- **VENUE:**

**Bratislava 15-16 October 2007
(Ruzinov hospital)**

- **PARTICIPANTS:**

Local coordinators and anesthesiologists

- **SIMULTANEOUS TRANSLATION WILL BE AVAILABLE**

PROGRAM

DAY 1 (15th OCTOBER)

9.00 – 9.15	Welcome	
9.15 – 9.30	Slovakia: Italy Twinning Project	<i>Kuba</i>
9.30 – 9.50	Coordination organizative model- Bratislava	<i>Lauro</i>
		<i>Vateha</i>
9.50 – 10.10	Coordination organizative model- Martin	
		<i>Miklusica</i>
10.10 – 10.30	Coordination organizative model- Banska Bystrica	
		<i>Sykora</i>
10.30 – 10.50	Coordination organizative model – Kosice	
		<i>Bena</i>
10.50 – 11.20	COFFEE	
11.20 – 11.40	Regional organizative coordination model in Italy	
		<i>Ridolfi</i>
11.40 – 13.00	Round table: proposal of coordination model in SK regions	

13.00- 14.00 **LUNCH**

14.00 – 14.20. **Model of national coordination in SK**
Kuba

14.20 – 14.40 Model of national coordination in Italy
Nanni Costa

14.40–15.40 Round table: proposal of national coordination model of donations in SK

15.40–16.00 Discussion

16.00 **Afternoon Tea**

Evening **TWINNING DINNER**

DAY 2 (16th OCTOBER)

8.30 – 9.30 Tools to increase organ procurement
Zanello

9.30 – 10.30 Comparison on safety of donor
Pettinao

10.30 – 11.00 **COFFEE**

11.00 – 13.00 Discussion on clinical cases related to course topics
Giordano(+ Zanello, Pettinao, Ridolfi+Vateha,Miklusica,Sykora,Bena)

13.00 – 13.30 Conclusions and final remarks

13.30 **LUNCH and HOME**

• LIST OF potential PARTICIPANTS TO STCOURSE

priezvisko	meno	titul	funkcia	odd	zdrav.zar.	adresa mesto
región Bratislava						
Kern	Peter	MUDr	primár	OAIM	FNsP Bratislava - Staré Mesto	Bratislava 1
Andrejčáková	Renáta	MUDr		KAIM	FNsP Bratislava - Ružinov	Bratislava 2
Riedel	Rudolf	MUDr	primár	D-KAIM	DFNsP	Bratislava 37
Vateha	Miloš	MUDr, CETC		KAIM	TC FNsP L. Déreza	Bratislava 37
Nechojdoma	Juraj	MUDr		OAIM	NsP sv. CaM	Bratislava 5
Molnár	Tibor	MUDr.		OAIM	NsP	Dunajská Streda
Orlická	Jana	MUDr		OAIM	NsP sv. Lukáša	Galanta
Pisár	Ján	MUDr	primár	OAIM	NsP	Komárno
Fehérová	Lýdia	MUDr		OAIM	NsP	Levice
Lichvárová	Ľudík	MUDr.	primár	OAIM	NsP	Malacky
Kertes	Marian	MUDr.		KAIM	FN	Nitra
Bodáková	Dagmar	MUDr		OAIM	NsP	Nové Zámky
Bedřichová	Daniela	MUDr		OAIM	Nem. A. Wintera, n.o.	Piešťany
Sabanoš	Rastislav	MUDr		OAIM	NsP	Skalica
Chalupka	Ľubomír	MUDr		OAIM	VšNsP	Šahy
Sabadošová		MUDr	primár	OAIM	NsP	Šaľa
Fábik	Alfonz	MUDr	primár	OAIM	NsP	Topoľčany
Jančovičová	Miriám	MUDr		KAIM	FNsP	Trnava
Rebek	Milan	MUDr		OAIM	MNsP	Zlaté Moravce
Šeboková	Katarína	MUDr		OAIM	NsP	Želiezovce

región Martin

Vavrová	Iveta	MUDr.		OAIM	NsP	Čadca
Rybanská	Jana	MUDr.		OAIM	NsP L. Nádaší-Jégeho	Dol. Kubín
Hegedúš	Viktor	MUDr.		OAIM	NsP	Lipt. Mikuláš
Miklušica	Juraj	MUDr.	II. chir. kl.		TC MFN	Martin
Plačková	Renáta	MUDr.		OAIM	NsP	Pov. Bystrica
Korenko	Milan	MUDr.		OAIM	ÚVN	Ružomberok
Kubiš	Peter	MUDr.		OAIM	NsP	Trstená
Serva	Branislav	MUDr.		OAIM	NsP	Žilina

región Banská Bystrica

Staš	Peter	MUDr.		chir.odd.	Mestská NsP n.o.	Bánovce n/Bebr.
Valky	Jozef	MUDr. CETC	primár	OAIM	TC NFDR	Banská Bystrica
Kenderessy	Peter	MUDr.		OAIM	DN	Banská Bystrica
Kernáč	Jozef	MUDr.		OAIM	Mestská NsP n.o.	Banská Štiavnica
Stano	Maroš	MUDr.		OAIM	NsP	Bojnice - Prievidza
Budová	Katarína	MUDr.		OAIM	NsP	Brezno
Barta	Iveta	MUDr.		OAIM	NsP	Hnúšťa
Domáň	Marián	MUDr.	primár	OAIM	NsP	Krupina
Tomaľová	Denisa	MUDr.		OAIM	NsP	Lučenec
Zongora	Jaroslav	MUDr.	primár	OAIM	NsP	Myjava
Krbúšik	Gabriel	MUDr.		OAIM	NsP n.o.	Partizánske
Vigodová	Tatiana	MUDr.	primár	OAIM	NsP n.o.	Revúca
Rajský	Róbert	MUDr.		OAIM	NsP	Rimavská Sobota
Šulík	Tomáš	MUDr.		OAIM	NsP	Trenčín
Horváthová	Katarína	MUDr.		OAIM	NsP n.o.	Veľký Krtíš
Krejčířová	Daniela	MUDr.		OAIM	NsP Vaše zdravie	Zvolen
Kukolík	Ladislav	MUDr.	primár	OAIM	NsP	Žiar n/Hronom

región Košice

Leško	Miroslav	MUDr.	primár	OAIM	NsP sv. Jakuba, n.o.	Bardejov
Šalátová	Zuzana	MUDr.	primár	OAIM	NsP A. Leňa	Humenné
Lapšanská	Katarína	MUDr.		OAIM	NsP V. Alexandra	Kežmarok
Michlík	Ján	MUDr.		OAIM	FNLP	Košice
Beňa	Ľuboslav	MUDr. CETC		Transpl	TC FNLP	Košice
Bazár	Juraj	MUDr.		D-JIS	DFN	Košice
Andráš	Tomáš	MUDr.		NCHK	FNLP	Košice
Bajtoš	Štefan	MUDr.		Chir odd	LVN	Košice
Boroš	Erich	MUDr.		Chir odd	Železničné zdravotníctvo	Košice
Rusnáková	Ivana	MUDr.		OAIM	1. súkromná nem., a.s.	Košice - Šaca
Feketeová	Esterá	MUDr.	primár	OAIM	NsP n.o.	Kráľovský Chlmec
Dzugasová	Adriana	MUDr.		OAIM	NsP	Krompachy
Hlubek	Martin	MUDr.		OAIM	NsP	Levoča
Smaržiková	Oľga	MUDr.		OAIM	NsP Š. Kukurú	Michalovce
Laincz	Anton	MUDr.	primár	OAIM	NsP	Poprad
Kožár	Ľuboš	MUDr.		II. KAR	FNsP J.A.Reimanna	Prešov
Labašová	Monika	MUDr.		OAIM	NsP sv. Barbory	Rožňava
Orinín	Norbert	MUDr.		OAIM	NsP	Snina
Zelený	Štefan	MUDr.	primár	OAIM	NsP	Spišská Nová Ves
Repka	Štefan	MUDr.		OAIM	NsP	Stará Ľubovňa
Sabanoš	Ladislav	MUDr.	primár	OAIM	NsP	Svidník
Domaracká	Eva	MUDr.		OAIM	NsP	Trebišov
Čandík	Peter	MUDr.		OAIM	NsP	Vranov n/Topľou

• STCourse report

Report regarding the outcome of the Short term Course for coordinators and anesthesiologists organized in Bratislava between 15 and 16 October 2007

The analysis regarding comparison between the National transplant coordination systems

The discussion led to general conclusions, shared by the Slovak and Italian professionals.

It would be advisable that **SCOT** consolidates its operational role inside the Slovak reality, cooperating in order to realize the efforts implemented during the donation process – realized at the moment only at a peripheral level – managing to create, in this way, a strategy based on the “national transplant network”.

Here there are the presumed instruments that could be used:

- 1) SCOT should be involved into the coordination of the donation process, as a leader in the “problem solving” field (transport , the centralization of the exams performed out of the donation site, the provision of national programs regarding the transplant for hyper immunized patients, etc.)
- 2) SCOT should provide the national guidelines concerning the criteria for inclusion in the waiting list and the allocation of organs donated, encouraging the exchanges between the different Transplant Centers in Slovakia.
- 3) The coordination of the import/export process that includes the organ, to or from other countries.
- 4) There should be a more penetrating role while informing the national media regarding the donation and transplant.
- 5) There should be taken a national informative campaign regarding the donation and the transplant.
- 6) Implement the on-line connection between the Donor Centers and the Transplant Centers, through a network aimed to optimize the donations.
- 7) The need of clear and nationwide known waiting lists.
- 8) Provide the entire network with the follow-up of the patients affected by organ transplant, as well as with the results of the tissue banks. The national recognition of the role played by the local coordinators in the donation process could encourage this strategy based on the “national transplant network”. This could also indicate to the responsables of the Slovak Health Authority an uniform national administrative position concerning this professional category, essential for the success of the system. There have been discussions regarding the necessary financial support aimed to optimize the system.

The comparison between different ways of regional transplant coordination

The discussion led to conclusions shared by the Slovak professionals (the transplant coordination from Bratislava, Martin and Kosice) and the Italian ones. The critical elements noticed inside the Slovak transplant system were the following:

- the local coordinator represents the critical step of the system, and he/she is the one that should be recognized and emphasized;
- even inside a system characterized by a high transplantologic culture, the continuous training has to be performed, especially when we speak about the eligibility criteria of the potential organ donors, according to patterns universally recognized;
- the communication between the four Slovak regional centers and the SCOT should be enhanced and realized in real-time;
- the centralization of the samplings and of all the exams performed on the potential donor continues to be the only solution to the present condition, even if the role of peripheral hospitals is still important from a donative point of view;
- the importance of the informative campaign led by SCOT was unanimously recognized.

The discussion regarding:

The strategies aimed to increase the number of donors,

The donor's safety,

The clinical cases

The discussion is considered to have been profitable for the reciprocal exchange of operational procedures.

Lorenza Ridolfi

(report approved by Mr Kuba)

ANNEX 2

• PROGRAMME OF MTCourses

COURSE MTC 1

Safety and Quality of Organs, Tissues and Cells for Human Application

A Training Course for Professionals working in Tissue or Cell Procurement, Processing, Storage or Distribution and Organ Transplantation

Venue: The Library, Ruzinov Hospital, Bratislava

DAY 1 (18TH SEPTEMBER)

9.00 – 9.15

Welcome

Dr Jan Koller/Dr Daniel Kuba

9.15 – 9.30	Participant introductions	
9.30 – 10.00	Slovakia:Italy Twinning Project	<i>Dr Augusto Lauro</i>
10.00 – 10.30	Slovak Legal Framework	<i>Dr Jan Koller/ Dr Daniel Kuba</i>
10.30 – 11.00	COFFEE	
11.00 – 11.30	Quality System Guide Overview	<i>Dr Deirdre Fehily</i>
11.30 – 11.50	Quality System Guide – Organs	<i>Dr Giuseppe Piccolo</i>
11.50 – 12.10	Quality System Guide – Cells	<i>Dr . Giovanni Migliaccio</i>
12.10 – 12.30	Quality System Guide – Tissues	<i>Dr Deirdre Fehily</i>
12.30 – 13.00	Quality System Guide - General Discussion	
13.00- 14.00	LUNCH	
14.00–15.30	Practical Examples of Quality System Management – participation of all attendees	<i>Facilitators: Stefan Poniatowski, Deirdre Fehily, Giuseppe Piccolo</i>
15.30–16.00	Discussion of Free Quality System cases from Slovak centres	<i>Facilitators: Stefan Poniatowski, Deirdre Fehily, Giuseppe Piccolo</i>
16.00	<i>Afternoon Tea</i>	

Evening

TWINNING DINNER

DAY 2 (19TH SEPTEMBER)

8.00 – 8.30	Donor Selection and Procurement	<i>Dr Maurizio Valeri</i>
8.30 – 9.30	Donor Selection Cases – participation of all attendees	<i>Facilitators: Dr Valeri, Dr Porta</i>

9.30 – 10.30	Implementing Quality System Requirements for Bone Marrow and Peripheral Blood Stem Cells – some challenges (including 20 minutes discussion)	<i>Dr Martino Introna</i>
10.30 – 11.00	COFFEE	
11.00 – 11.40	Implementing Quality System Requirements for Tissues – some challenges (including 10 minutes discussion)	<i>Stefan Poniatowski</i>
11.40 – 12.20	Achieving quality, safety and sufficiency in organ donation and transplantation (including 10 minutes discussion)	<i>Dr Piccolo</i>
12.20 – 13.00	EU Legal Framework	<i>Thomas Bregeon, European Commission</i>
13.00 – 13.30	Conclusions and final remarks	<i>Dr Jan Koller/Dr Daniel Kuba</i>
13.30	LUNCH and HOME	

COURSE MTC 2

Safety and Quality of Organs, Tissues and Cells for Human Application

A Training Course for Professionals working in Tissue or Cell Procurement, Processing, Storage or Distribution and Organ Transplantation

Venue: The Library, Ruzinov Hospital, Bratislava

DAY 1 (20TH SEPTEMBER)

9.00 – 9.15	Welcome
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		<i>Dr Jan Koller/ Dr Daniel Kuba</i>
9.15 – 9.30	Participant introductions	
9.30 – 10.00	Slovakia:Italy Twinning Project	<i>Dr Augusto Lauro</i>
10.00 – 10.30	EU Legal Framework	<i>Thomas Bregeon, European Commission</i>
10.30 – 11.00	Slovak Legal Framework	<i>Dr Jan Koller/ Dr Daniel Kuba</i>
11.00 – 11.30	COFFEE	
11.30 – 12.00	Quality System Guide Overview	<i>Dr Deirdre Fehily</i>
12.00 – 12.15	Quality System Guide – Organs	<i>Dr Giuseppe Piccolo</i>
12.15 -12.30	Quality System Guide – Cells	<i>Dr . Giovanni Migliaccio</i>
12.30 – 12.45	Quality System Guide – Tissues	<i>Dr Deirdre Fehily</i>
12.45 – 13.00	Quality System Guide - General Discussion	
13.00- 14.00	LUNCH	
14.00–15.30	Practical Examples of Quality System Management – participation of all attendees	<i>Facilitators: Stefan Poniowski, Deirdre Fehily, Giuseppe Piccolo</i>
15.30–16.00	Discussion of Free Quality System cases from Slovak centres	<i>Facilitators: Stefan Poniowski, Deirdre Fehily, Giuseppe Piccolo</i>
16.00	<i>Afternoon Tea</i>	

Evening

TWINNING DINNER

DAY 2 (21ST SEPTEMBER)

8.00 – 8.30	Donor Selection and Procurement
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		<i>Dr Maurizio Valeri</i>
8.30 – 9.30	Donor Selection Cases – participation of all attendees	
		<i>Facilitators: Dr Valeri, Dr Porta</i>
9.30 – 10.30	Implementing Quality System Requirements for Bone Marrow and Peripheral Blood Stem Cells – some challenges (including 20 minutes discussion)	
		<i>Dr Martino Introna</i>
10.30 – 11.00	COFFEE	
11.00 – 12.00	Implementing Quality System Requirements for Tissues – some challenges (including 20 minutes discussion)	
		<i>Stefan Poniatowski</i>
12.00 – 13.00	Achieving quality, safety and sufficiency in organ donation and transplantation (including 20 minutes discussion)	
		<i>Dr Piccolo</i>
13.00 – 13.30	Conclusions and final remarks	
		<i>Dr Jan Koller/Dr Daniel Kuba</i>
13.30	LUNCH and HOME	

COURSE MTC 3

Safety and Quality of Organs, Tissues and Cells for Human Application

A Training Course for Professionals working in Tissue or Cell Procurement, Processing, Storage or Distribution and Organ Transplantation

Venue: The Library, Ruzinov Hospital, Bratislava

DAY 1 (25TH SEPTEMBER)

9.00 – 9.15	Welcome
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Dr Jan Koller/Dr Daniel Kuba

9.15 – 9.30	Participant introductions	
9.30 – 10.00	Slovakia:Italy Twinning Project	
		<i>Dr Augusto Lauro</i>
10.00 - 10.30	Slovak Legal Framework	
		<i>Dr Jan Koller/Dr Daniel Kuba</i>
10.30 - 11.00	COFFEE	
11.00 - 11.30	Quality System Guide Overview	
		<i>Dr . Fiorenza Bariani</i>
11.30 – 11.50	Quality System Guide – Organs	
		<i>Dr Giuseppe Piccolo</i>
11.50 – 12.20	Quality System Guide – Tissues and Cells	
		<i>Dr Deirdre Fehily</i>
12.20 – 13.00	Quality System Guide - General Discussion	
13.00- 14.00	LUNCH	
14.00–15.30	Practical Examples of Quality System Management – participation of all attendees	
		<i>Facilitators: Valéria Jarabinska, Deirdre Fehily, Giuseppe Piccolo</i>
15.30–16.00	Discussion of Free Quality System cases from Slovak centres	
		<i>Facilitators: Valéria Jarabinska, Deirdre Fehily, Giuseppe Piccolo</i>
16.00	<i>Afternoon Tea</i>	

Evening

TWINNING DINNER

DAY 2 (26TH SEPTEMBER)

8.00 – 8.30	Donor Selection and Procurement	
		<i>Dr Maurizio Valeri</i>
8.30 – 9.30	Donor Selection Cases – participation of all attendees	
		<i>Facilitators: Dr Valeri, Dr Elisa Pianigiani</i>
9.30 – 10.30	Implementing Quality System Requirements for Bone Marrow and Peripheral Blood Stem Cells – some challenges (including 20	

	minutes discussion)	
		<i>Dr Letizia Lombardini</i>
10.30 – 11.00	COFFEE	
11.00 – 11.40	Implementing Quality System Requirements for Tissues – some challenges (including 10 minutes discussion)	<i>Dr Elisa Pianigiani</i>
11.40 – 12.20	Achieving quality, safety and sufficiency in organ donation and transplantation (including 10 minutes discussion)	<i>Dr Piccolo</i>
12.20 – 13.00	EU Legal Framework	
		<i>Eduardo Fernandez Zincke/Caroline Trouet, European Commission</i>
13.00 – 13.30	Conclusions and final remarks	
		<i>Dr Jan Koller/Dr Daniel Kuba</i>
13.30	LUNCH and HOME	

COURSE MTC 4

Safety and Quality of Organs, Tissues and Cells for Human Application

A Training Course for Professionals working in Tissue or Cell Procurement, Processing, Storage or Distribution and Organ Transplantation

Venue: The Library, Ruzinov Hospital, Bratislava

DAY 1 (27TH SEPTEMBER)

9.00 – 9.15	Welcome	
		<i>Dr Jan Koller/Dr Daniel Kuba</i>
9.15 – 9.30	Participant introductions	

9.30 – 10.00	Slovakia:Italy Twinning Project	<i>Dr Augusto Lauro</i>
10.00 – 10.30	EU Legal Framework	<i>Eduardo Fernandez Zincke/Caroline Trouet, European Commission</i>
10.30 – 11.00	Slovak Legal Framework	<i>Dr Jan Koller/ Dr Daniel Kuba</i>
10.30 - 11.00	COFFEE	
11.00 - 11.30	Quality System Guide Overview	<i>Dr . Fiorenza Bariani</i>
11.30 – 12.00	Quality System Guide – Organs	<i>Dr Giuseppe Piccolo</i>
12.00 – 12.20	Quality System Guide – Tissues and Cells	<i>Dr Deirdre Fehily</i>
12.20 – 13.00	Quality System Guide - General Discussion	
13.00 - 14.00	LUNCH	
14.00–15.30	Practical Examples of Quality System Management – participation of all attendees	<i>Facilitators: Valéria Jarabinska, Deirdre Fehily, Giuseppe Piccolo</i>
15.30–16.00	Discussion of Free Quality System cases from Slovak centres	<i>Facilitators: Valéria Jarabinska, Deirdre Fehily, Giuseppe Piccolo</i>
16.00	<i>Afternoon Tea</i>	

Evening

TWINNING DINNER

DAY 2 (28TH SEPTEMBER)

8.00 – 8.30	Donor Selection and Procurement	<i>Dr Maurizio Valeri</i>
8.30 – 9.30	Donor Selection Cases – participation of all attendees	<i>Facilitators: Dr Valeri, Dr Elisa Pianigiani</i>

9.30 – 10.30	Implementing Quality System Requirements for Bone Marrow and Peripheral Blood Stem Cells – some challenges (including 20 minutes discussion)	<i>Dr Letizia Lombardini</i>
10.30 – 11.00	COFFEE	
11.00 – 12.00	Implementing Quality System Requirements for Tissues – some challenges (including 10 minutes discussion)	<i>Dr Elisa Pianigiani</i>
12.00 – 13.00	Achieving quality, safety and sufficiency in organ donation and transplantation (including 10 minutes discussion)	<i>Dr Piccolo</i>
13.00 – 13.30	Conclusions and final remarks	<i>Dr Jan Koller/ Dr Daniel Kuba</i>
13.30	LUNCH and HOME	

ANNEX 3

Draft of LEAFLET for general public

Importance of organ, tissue and cell donation

Transplantation of organs, cells and tissues are acknowledged as effective therapies across a wide range of both fatal and non-fatal disease.

Nowadays, thanks to transplantation, we can offer a better life to those who are suffering.

Transplant means a new life: recipients would get back to normal life, they would work again, have children, play sports, they would LIVE!

This is the meaning of donation. Donate organs, tissues and cells means donate life. Choosing to be a donor is choosing to be active part of a solidaristic community. Helping an ill person is helping the society to grow up! Everyone of us has an unlimited possibility to offer gifts for life.

Donation in Slovak Republic

to be completed by Dr. Kuba

Transplant programs presently running in Slovak Republic, organization of transplant centres, coordinating centres

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 centers

Transplant centre University Derrer's hospital, Bratislava (kidneys, liver)

Transplant centre, Slovak institute for heart diseases, Bratislava, (heart)

Transplant centre University hospital, Martin (kidneys)

Transplant centre Roosevelt hospital, Banska Bystrica (kidneys, pancreas)

Transplant centre, University hospital, Košice, (kidneys)

Children Cardio center, Bratislava (heart)

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:

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.Roosevelt Hospital, Banská Bystrica, eye bank

Hemopoietic Cell Banks (HPC banks) - 4 in Bratislava, 1 in Banska Bystrica, 1 in Martin, 1 in Kosice, 1 in Presov

Children Faculty Hospital, Bratislava (blood cells, bone marrow)

Faculty Hospital, Bratislava – Petržalka (blood cells)

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

Slovak Register of Cord Haemopoetic Cells (EUROCORD), Bratislava, cord blood bank

Privat Hospital Kosice - Saca Tissue Bank

The twinning program and its aims

A twinning project between the Italian and Slovak Ministries of Health, funded by the European Commission, began in December 2006 with the aim of improving the safety, quality and availability of organs, tissues and cells in the Slovak Republic. The project, running for two years, aims at introducing quality management principles for organ, tissue and cell transplantation, to assure highest possible levels of public health protection, that means the protection of the patient.

Some figures on donation and transplantation in Europe (Transplant Newsletter-Council of Europe)

Range of pmps in different EU countries, waiting lists and consequent importance of donation

5 Frequently Asked Questions, **to be completed by Dr.Kuba**

References

www.health.gov.sk

www.ncot.sk

Draft of BROCHURE

Index

The European policy in the field of organs, tissues and cells donation and transplantation.

The Slovak legislation

The twinning program between Italy and Slovak Republic

Critical aspects in the donor management and transplant process

The QMS guidelines

Annex: CD with guidelines

The European policy in the field of organs, tissues and cells donation and transplantation

Benefits of transplantation

Organ transplantation is the most cost-effective treatment for end-stage renal failure, and it is the only available treatment for end-stage failure of organs such as the liver, lung, and heart. Transplantation of tissues such as corneas, cardiovascular tissues, bone, tendons and skin are all well-established therapeutic techniques. Although most of these transplants are not lifesaving, they can offer major therapeutic benefits to a wide range of patients. Cell transplantation, particularly haematopoietic progenitor cell (HPC) transplantation, is also well established and can be lifesaving in the treatment of severe immunodeficiency syndromes and many types of haematological malignancy.

European efforts

The complex process of donation and transplantation requires the adoption of high quality and safety standards as well as a good cooperation and harmonization of such standards among the Member States. In this light, different European authorities, such as the Health Committee of the Council of Europe and the European Commission concentrated their efforts to improve quality and safety of transplant process. As concerns legislation, in the field of tissue and cells, the European Union adopted the 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 the two related Technical Directives (nn.17 and 86 published in 2006).

The first Directive (23/2004) states the general requirements, detailed in the two following technical directives. The 17/2006 establishes the donor selection criteria and the mandatory tests, including the provision for acceptance of non complying donations by risk assessment and a full list of exclusion criteria based on medical and social history and validity of blood sample. The mandatory tests includes

1. Anti-HIV 1 and 2
2. HbsAg

3. HBV anti-core
4. Anti-HCV
5. Syphilis (reactive test result – donor may still be eligible by risk assessment)

The second technical directive 86/2006 focuses on the requirements for the accreditation of establishments and processes, particularly on:

- Quality system
- Staff training requirements
- Validation (through literature and retrospective analysis of own data)
- Risk assessment
- Reporting and communication of serious adverse events and reactions

All the European recommendations and legislation can be found on the following websites:

Council of Europe SDPTO

European Commission Pub Health

Slovak legislation

The following Slovak laws and Ministry of Health guidance constitute the legal framework for organ, tissue and cell transplantation in Slovakia:

- Law number 576/2004
This is the main transplant law which governs procurement, storage and transport of organs, tissues and cells.
- Law number 282 of April 19th 2006 represents an updating of Law number 576 to incorporate the requirements of other new legislation, including Directive 2004/23/EC (see 2.0 below).
- Governmental Decree 20/2007, published on December 20th 2006, is the transposition into Slovak law of Directive 2006/17/EC (see 2.0 below).
- The Slovak Ministry of Health Guidance published on the 3rd December 2006 (28610/2006 – OZSO) expanded on Law number 576, including greater details on organ donor selection requirements.

All legislation is attached as appendixes to QMS guidelines.

The twinning program between Italy and Slovak Republic

Funded by the European Commission (DG Enlargement) through the Phare program, the twinning project entitled '**Improvement of the Safety, Quality and Availability of Organs, Tissues and Cells**' between the Italian and Slovak Ministries of Health began in December 2006 and will continue for 2 years. The main components of the project are

- audits of existing activities;
- design and implementation of a Quality Management System Guide

- training courses;
- technical assistance in the development of a unified Information Technology system
- information and dissemination

The audits of organ, tissue and cell procurement and transplant centre allowed to draw a picture of present features of the Slovak system, focusing on its strengths and weaknesses. The audit reports set the grounds for the design of the QMS guidelines.

Critical aspects in the donor management and transplant process

The results of audit visits were published on the Health Ministry website (www.health.gov.sk) and presented during a conference held in March 2007 in Bratislava.

Among the identified critical aspects in the donor management and transplant process, the following general needs were evinced:

- national competent authorities should be identified in order to coordinate, standardize and monitor the national donation and transplantation system;
- a national transplant community that shares knowledge, know-how, best practices and information concerning procurement, banking and transplant activities;
- a consistent quality system that identify and cover all steps of the process from donor identification to transplant;
- a clear-cut definition of roles and tasks for involved personnel, taking into account the importance of training needs and educational programmes;
- clear job descriptions for each function and a clear organizational chart, with a description of the responsibilities for each activity and process;
- periodical audits by internal and external experts in order to ensure a continuous monitoring and improvement of the system;
- the adoption of better procedures always ensuring adequate safety levels for protection of healthcare professionals;
- necessity of adequate tools and facilities where processes take place, in the respect of existing rules.

The QMS guidelines

The Quality Management System Guide (QMSG) 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 the three European Union Directives 2004/23/EC, 2006/17/EC, 2006/86/EC. A

number of Italian, Slovakian 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 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.