PHARE 2004
STANDARD PROJECT FICHE

1. Basic Information

1.1 CRIS Number (Year 1): RO-Phare 2004/016-772.03.09

Title: **Strengthening the capability of the Romanian Blood Transfusion System to comply with EC requirements for Quality and Safety of Human Blood and Blood Components**

1.2

1.3 Sector:
1.4 Location: Romania

1.5 Duration: 2 years

2. Objectives

2.1. Overall Objective(s):

Capacity building to implement the provisions of Directive 2002/98/EC in the Romanian Blood Transfusion System.

2.2 Project purpose:

a) To ensure compliance with Article 11 of Directive 2002/98/EC by establishing a quality system based on the principles of good practice.

b) To ensure quality control and traceability of each single blood donation and each single blood unit and components thereof in accordance with the provisions of Articles 11 & 14 of Directive 2002/98/EC;

c) To comply with the requirements for storage, transport and distribution of Article 22 of Directive 2002/98/EC;

d) To comply with the provisions of Article 20 of Directive 2002/98/EC in relation to measures to encourage voluntary and unpaid donations.

2.3 Accession Partnership and NPAA priority

Accession Partnership: Transpose and implement legislation on public health and develop a national system for surveillance and control of communicable diseases and a health monitoring information system; strengthen the capacity to manage health sector reform in a comprehensive manner by improving strategic planning for human and financial resources so as to make efficient use of public funds while ensuring equal access to health care.

NPAA:

Current Situation

The Romanian health system is in a process of major structural reform; in this respect, concrete action programs and reform measures were initiated in specific fields of activity including: reform of the public administration in the sanitary system, increasing the quality of health services, improvement of the national system of emergency and legislative harmonisation with the acquis communautaire.

Short-Term Priorities

Developing of a IT monitoring system in the field of public health:
Establishing a legislative framework to allow the information exchange between the Ministry of Health and other ministries, institutions and organizations regarding the health determinants;

Medium-Term Priorities

Development of the national epidemiological surveillance system and control of communicable diseases

Roadmap for Romania

Chapter 13: Social Policy and Employment

Romania should focus further efforts on the adoption of a new labour code, continued transposition and implementation of the health and safety at work acquis (..).Further work is also needed with regard to inter-institutional co-operation, decentralizing social responsibilities to the local level, budgetary organisation, ensuring adequate staff numbers and effective training of personnel.(..).Attention needs to be given to ensuring commitments made in that process are respected

Medium term
Complete transposition of acquis on health (…)
Reorganise the national surveillance and control system of communicable diseases in order to comply with the acquis and intensify staff training
Ensure the development of a health information system which meets Community standards

2.4. Contribution to National Development Plan (and/or Structural Funds Development Plan/SDP)

Not applicable.

2.5 Cross Border Impact

Not applicable.

3. Description

3.1 Background and justification:

Considerable development of processes and equipment will be required at the Romanian BTS to ensure compliance will all applicable provisions of directive 2002/98/EC to blood establishments. Modifications of existing provisions or implementation of new ones will be required by

- Article 9 (responsible person);
- Article 10 (personnel);

- Article 11 (quality system for blood establishments);
- Article 12 (documentation);
- Article 13 (record keeping);
- Article 14 (Traceability);
- Article 15 (notification of serious adverse events);
- Article 16 (provision of information to prospective donors);
- Article 17 (information required from donors);
- Article 18 (eligibility of donors);
- Article 19 (examination of donors);
- Article 20 (voluntary and unpaid donation);
- Article 22 (storage, transportation and distribution conditions);
- Article 29 (technical requirements and their adaptation to technical and scientific progress).

The strength of the Romanian BTS lies in a well structured national organization comprising the National Institute of Transfusion Haematology, eight major centers and thirty two local centers. This mature structure provides a means of implementing and ensuring quality initiatives and other changes in a controlled and cost effective manner.

Considerable challenges to compliance with Directive 2002/98/EC are posed, however by several major factors.

The quality system is relatively undeveloped – personnel solely dedicated to quality assurance, quality control and quality management are lacking; documentation requires extensive development: quality manuals or product master files, process flows, validation plans and processes, standard operating procedures, training manuals and logs, change control and its documentation all require to be developed.

Quality assurance and control, the security of product release and the ability to conduct adequate traceability and recall are compromised by total reliance on manual records. Extensive shipping of components between centers and hospitals further complicates this issue.

Equipment and premises have suffered from long-term financial constraints in the BTS. Considerable upgrading and updating will be required in the short to medium term.

Donation levels are not sufficient to meet national requirements for blood or blood components: in 2003, a total of 346,023 allogeneic whole blood units were collected – approximately one third of the EU average; this was sufficient to meet two thirds of hospital requests for blood and plasma. Platelet demand was met half the time, and cryoprecipitate requests 40% of the time. This level of donation and collection is clearly a very major problem that will be compounded by improvements in provision of hospital services in the future. This problem is made worse by a high rate of positivity for infectious disease markers in blood donors, both in new donors and in regular donors. While this may have several contributory causes, it reflects the problems encountered by the necessity to rely on a significant level of inducement for blood donors, including 2 days off work along with food and transport vouchers. This causes the residual risk of disease transmission by blood transfusion in Romania to rise to a level many times that in EU member states. The introduction of new mobile units provides the opportunity to develop a new approach to donor recruitment and retention. For example it may be used to emphasize the importance of blood donation to college and university students. It may also be used to collect donations in areas not previously visited. This in turn affords a chance to alter the connection between reward and donation.

There is a lack of the equipment and procedures necessary to provide a proper system to guarantee the integrity and quality of blood and components during transportation between blood centres and from blood centers to hospitals.

In addition to their inherent problems and the compromise to health care that they constitute, the issues outlined above have prevented the Romanian BTS from finding a partner willing to provide a contract fractionation service for the manufacture of blood derivatives from Romanian plasma. This has contributed to difficulties in providing adequate supplies for patients with haemophilia, among other problems. In 2003 the usage of factor VIII in Romania was 0.08 units per capita, less than one tenth the annual usage in EU member states.

3.2 Sectoral rationale

Not applicable.

3.3 Results

3.3.1 Project

a) To ensure compliance with Article 11 of Directive 2002/98/EC by establishing a quality system based on the principles of good practice
b) To ensure quality control and traceability of each single blood donation and each single blood unit and components thereof in accordance with the provisions of Articles 11 & 14 of Directive 2002/98/EC;

c) To comply with the requirements for storage, transport and distribution of Article 22 of Directive 2002/98/EC

d) To comply with the provisions of Article 20 of Directive 2002/98/EC in relation to measures to encourage voluntary and unpaid donations.

3.3.1.2 Results:

a) National Quality System compliant with the specifications developed under Article 29(h) of Directive 2002/98/EC in place.

b) National computer system for quality assurance, quality control, traceability and recall in place.

c) National cold chain specified in accordance with requirements of Directive 2003/33/EC. Annex IV implementing technical requirements of Directive 2002/98/EC.

d) Mobile donation collection increasing the national blood supply and decreasing the reliance on donor incentives:

3.4 Activities (including Means)

a) The following activities will be carried out in order to establish a National Quality System compliant with the specifications developed under Article 29(h) of Directive 2002/98/EC in place.

I. Training National QA Director and Quality Managers for compliance with Article 9 of Directive 2002/98/EC.

Means:

Workshops provided by external experts; overseas training for National QA Director and Quality Managers in Quality Departments with appropriate training facilities and expertise in EU Member States. This training will include all aspects of quality systems and quality management: document management, change control procedures and policies; quality assurance of all processes; quality control of reagents, material and products; product release and recall, etc.

II. Documentation:

- A complete description of all activities in the Romanian BTS, along with process maps and flows;
- A complete set of Standard Operating Procedures covering all activities in all centers;
- Change control and validation procedures and documentation in place;
- Additional documentation requirements to be specified under Article 29(h) of Directive 2002/98/EC in place.

Means:

a)External expert together with National Quality Director and Quality Managers.

b) The following activities will be carried out in order to establish a national computer system for quality assurance, quality control, traceability and recall:

I. Documentation.
Develop user requirement specifications for national computer system.

Means:
Short and medium term external experts

II. Training.
Train key personnel in order to set up and use the national computer system.

Means:
Overseas visits by project team to three sites to acquire detailed knowledge of available systems.
Workshops and assistance by external IT consultant for project team and key persons.

III. Networked installation in key sites for evaluation and development of the system and the expertise in the RBTS.

Means:
Purchase of IT equipment and software;
External expert support.

c) The following activities will be carried out in order to establish a national cold chain specified in accordance with requirements of Directive 2004/33/EC Annex IV implementing technical requirements of Directive 2002/98/EC.

I. Documentation.
Requirements for equipment and procedures for cold storage and transport, including validation and monitoring.

Means:
Short and medium term expert.

II. Training.
One week training course for key staff in the blood
Means:
Short term expert.

d) The following activities will be carried out in order to establish a mobile donation collection increasing the national blood supply and decreasing the reliance on donor incentives:

I. Installation of mobile facilities in key sites.

Means:
Purchase, equipping and introduction into service of buses equipped as donation collection units with beds, assessment facilities, resting spaces etc.

II. Assessment of impact of mobile collection on recruiting new donors in previously unvisited locations.

Means:
Quantitative data collection and analysis by internal experts.

3.5 Linked Activities:

The Phare Programme RO910603-B00201 (1993-1995) provided the necessary financial support for the acquisition of “Medical equipments for blood collection and testing for BTCs.” ELISA equipment, freezers, medical devices for preparation of monoclonal antibodies, etc. were introduced in the Romanian Transfusion Service.
Between 1994-1997, the Contract for plasma fractionation for Romania, Europe – CEE was under run, providing blood products (FVIII and FIX concentrates, albumin, Ig) in exchange of FFP provided.
The programme IHB-2045 with the World Bank provided the funds for the introduction of anti HCV testing in Romania.
The Phare Program RO 9712 LOT 1-3 (1998), called “Provision of IT equipment for MOH” and RO9712-L003-0201, called “Equipment for laboratory”, facilitated the acquisition of other necessary medical devices.
The Phare Program “Approximation of Legislation in the Pharmaceutical Sector”, developed during 1998-2000 offered the training sessions on “Financial Management in BTC” and “QAS implementation in blood service”.

3.6 Lessons learned:

We have learned from the experience that emerged from the Phare programme Health Care Reform RO 9712-L003. This programme aimed to develop tools for a better regulation of the drug market, to support the improvement of the quality assurance system, to ensure sufficient blood supply of good quality. All these objectives has been “satisfactory” fulfilled; as a consequence, 3 workshops have been held for 140 persons to improve the general financial management and structure of the blood transfusion service nationally, 2 workshops for 120 persons have been addresses clinical issues in blood transfusion and use, 20 persons were enabled to attend an international convention on blood transfusion practice, 3 persons have been on study tours to improve their skills in the field of blood transfusion. This Phare programme experience demonstrated that a strong determination, a governmental support and a valuable priority action plan which enable the Acquis could guarantee the success. Besides these essential aspects we must think at the entering into force of a national legislation in accordance with the EC requirements, an efficient specialised training (medical universities, etc.), strengthening the institutional capacity in order to contribute to general confidence both on the quality of donated blood components and in the health protection of donors, to attain national self-sufficiency and to enhance confidence in the safety of the transfusion chain.

However, the programme showed that the principles of horizontality of staff training, an improved cooperation between all the Romanian stakeholders and civil organisations which report data can improve the timing and quality of data. Setting an accurate data base on the blood national transfusion services is an essential tool of this programme.

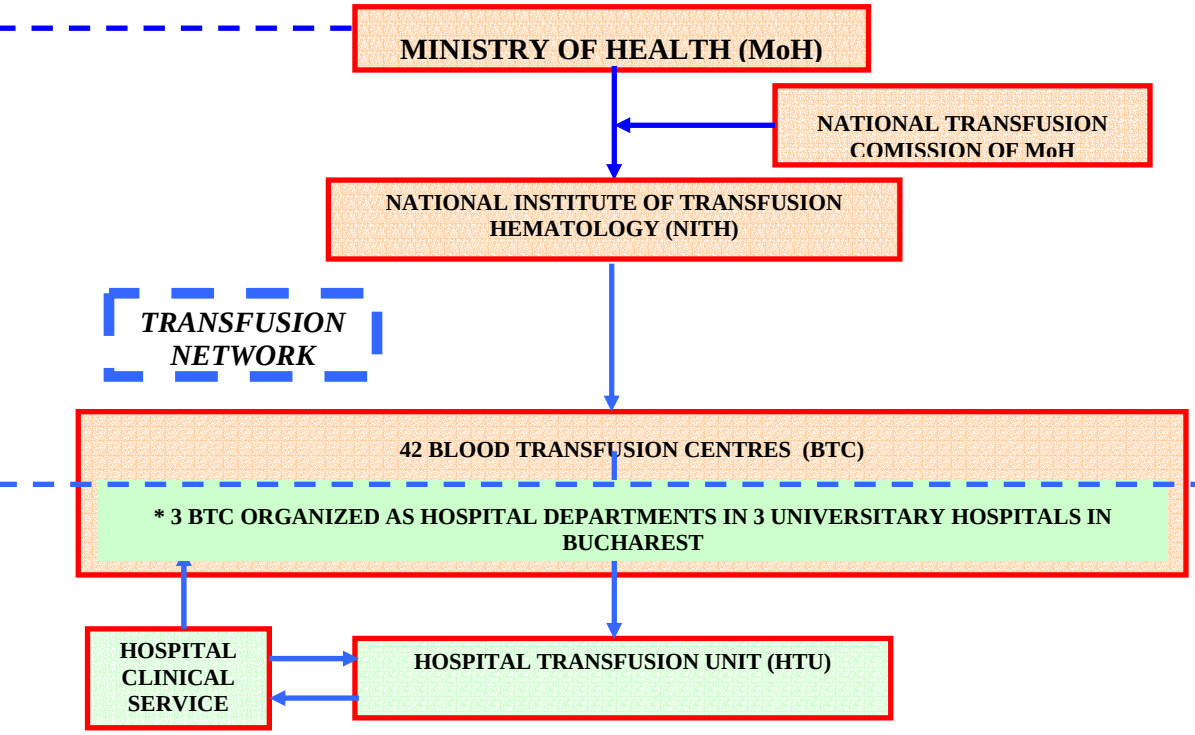
4 Institutional Framework

The transfusion activity in Romania is coordinated by the Ministry of Health through its specialized institutions. The National Institute of Transfusion Haematology coordinates, organizes and verifies the activity of the entire national blood transfusion service, scientific research and transfusion medicine education. The advisory body of MoH in transfusion medicine is the National Transfusion Commission.

The Blood Transfusion Centres represent the basic “blood establishment” units, responsible to organize the whole transfusion activity at county level, from promotion and collection to distribution of blood and blood components to hospital transfusion units. There are 42 BTCs, 1 for each of the 40 counties, 1 for Bucharest and 1 belonging to the military health network. In Bucharest there are 3 hospital - based transfusion departments in 3 universitary hospitals; they belong to the BTC of Bucharest from the technical point of view.

During the implementation of this project, NITH and all the BTCs will be involved, being the beneficiaries of the project, as parts of the national blood transfusion system.

The chain of command is as follow:



We do not expect that the results of our programme could initiate changes in the chain of command as presented.

A steering committee or management board of the network will be formed by the Ministry of Health. It is advisable that the steering committee has the following members: the Secretary of State, the Senior Programme Officer, 1 representative of Phare Implementation Unit_ the General Manager of NITH, 1 representative of regional/ county BTC.

A secretarial structure (Advisory Committee) of the steering committee will coordinate all the technical issues of the project.

Detailed Budget

Year 1/Phase 1	**EU**	**Support**				
	Investment Support	Institution Building	**Total EU (=I+IB)**	**National Co-financing**	**IFI***	**TOTAL**
Project 1						
Contract 1	-	1,200,000	1,200,000	-		
Contract 2	1,500000	-	1,500,000	500,000		2,000,000
Total	1,500 000	1,200,000	2,700,000	500,000		3,200,000

** In cases of co-financing only*
Note: expenditure on equipment should be put under Investment

Contract 1: Technical assistance including training.
Contract 2: Investment support.

The co-financing (€500,000) is assured from governmental funds i.e. the budget of the Ministry of Health . These funds shall be included in the new budget for 2005 of the Ministry of Health.

5 Implementation Arrangements

5.2 Implementing Agency

The Central Finance and Contracts Unit (CFCU) is the contracting authority. The financial management of the Program will be under the responsibility of the CFCU. The nominated Program Authorizing Officer (PAO), who is a Secretary of State from the Ministry of Finance, and the Deputy PAO, who is the General Director of the CFCU, are responsible for contracting and accounting. The responsibilities of the CFCU also cover finalization of contract dossiers for approval, of Technical contracts, and maintenance of financial records for audit purposes.

The Central Finance and Contracts Unit
Ms Jeana BUZDUGA, Director, PAO
Ministry of Finance / CFCU; 6-8 Magheru Blvd., 5th Floor, Bucharest, District 1
Tel: (4021) 301 93 01
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Implementing Authority

Ministry of Health

Phare Projects Implementation Unit
1-3 Cristian Popisteanu Str., Sector 1 Bucharest
Tel/Fax: 021 312 14 33, Tel: 021 3072 620
E-mail: ltronaru@ms.ro

Main Beneficiary:
National Institute of Transfusion Hematology

Beneficiaries:

Blood Transfusion Centers (1 for each district)

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6.2. Twinning
Not applicable.

6.3. Non-standard aspects

The Practical Guide to Contract Procedures Financed from the EC general Budget will be strictly followed.

6.4. Contracts
Contract 1: Technical Assistance including training: 1.2 MEuro

Contract 2: Investment Support: 1.5 MEuro

7. Implementation Schedule
7.1 Start of tendering/call for proposals
January 2005
7.2 Start of project activity
March 2005
7.3 Project completion
End of 2006

8.Equal Opportunity
The equal opportunity for women and men in the project will be assured by the equal gender proportion within the teams of international and local experts, and by the equitable distribution of their responsibilities.

9.Environment
No initial environment screening has been completed so far but thorough studies shall be carried out along with the project. After completing the environmental study an environmental impact statement shall be elaborate.

10.Rates of return
Not applicable.

11.Investment criteria (applicable to all investments)

11.1. Catalytic effect

Due to the poor national financing, all the outcomes of the above- mentioned project would be delayed unless the receipt of suitable EC funds. This issue shows once again the importance of the European funds for the fulfilment of the project.

11.2. Co-financing

Romanian Government is determined to allocate the co-financing for the investment support, consisting in 500.000 Euro.

11.3. Additionality

In conformity with the nature of the project, the implementation of *acquis communautaire*, no other financing agency will be involved.

11.4 Project readiness and size

The first-line assessment of the profile and size of investment part of the project (equipment and materials) is carried out within the framework of establishing the Technical Specification Report.
In order to develop the investment support component, it is advisable that a PPF team will make a pre-feasibility study and the technical specifications. All these tasks would be realised in order to have all the tender documentation prepared in 6 months after the approval of .financing memorandum 2004

11.5 Sustainability

The financial and institutional sustainability of the investment is foreseen within the framework of the project.

11.6. Compliance with state aids provisions

Government contribution is according to the Europe Agreement.

12.Conditionality and sequencing

At this stage we cannot identify with high degree of precision any conditioning effects.

In terms of impact by the end of 2007, according to the project, the endowment with adequate equipment and materials must be concluded as much as the main form of the personnel training.

ANNEX 1

Log frame

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number	
Strengthening the capability of the Romanian Blood Transfusion System to comply with EC requirements for Quality and Safety of Human Blood and Blood Components	Contracting period begins January 2006	Disbursement period begins January 2007
	Total budget: **3.200.000 EU**	Phare budget **2.700.000 EU**

Overall objective	**Objectively verifiable indicators**	**Sources of Verification**
Capacity building to implement the provisions of Directive 2002/98/EC in the Romanian Blood Transfusion System	Capability achieved in Romanian Blood Transfusion System to implement requirements of Directive 2002/98/EC	- National statistics - Quality assurance control -The Official Journal - Regular BTC activity reports

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
a) To ensure compliance with Article 11 of Directive 2002/98/EC by establishing a quality system based on the principles of good practice.	Quality systems in place; provisions of Article 11.1 achieved	Staff records; quality documentation available.	- MOH commitment and support
b) To ensure quality control and traceability of each single blood donation and each single blood unit and components thereof in accordance with the provisions of Articles 11 & 14 of Directive 2002/98/EC.	Provisions of Article 14 achieved	Staff records; quality documentation available.	- MOH commitment and support

c) To comply with the requirements for storage, transport and distribution of Article 22 of Directive 2002/98/EC.	Provisions of Article achieved	Staff records; quality documentation available.	- MOH commitment and support
d) To comply with the provisions of Article 20 of Directive 2002/98/EC in relation to measures to encourage voluntary and unpaid donations	Provisions of Article 22 achieved	Staff records; quality documentation available.	- MOH commitment and support

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
a) National Quality System compliant with the specifications developed under Article 29(h) of Directive 2002/98/EC in place.	National Quality Director in post; 8 additional quality managers in post in the major centers; Job descriptions and training records in place for all staff. A complete description of all activities in the Romanian BTS, along with process maps and flows in place; A complete set of Standard Operating Procedures covering all activities in all centers in place; Change control and validation procedures and documentation in place;	Staffing records and documentation available at RBTS sites	- Government commitment and support - Good coordination and real-time information transfer from all BTC. - International cooperation

	Additional documentation requirements to be specified under Article 29(h) of Directive 2002/98/EC in place.		
b) National computer system for quality assurance, quality control, traceability and recall in place.	National Computer System defined; installation of donor and quality modules live in 4 sites; national IT manager in post.	Staffing records and documentation available at RBTS sites	- Government commitment and support - International cooperation
c) National cold chain specified in accordance with requirements of Directive 2004/33/EC Annex IV implementing technical requirements of Directive 2002/98/EC.	Overall specification of equipment and procedures for cold chain transportation and storage completed, including complete equipment specifications and lists for storage, transport, monitoring and quality assurance equipment; Purchase of full complement of national requirement for transportation boxes and data logging equipment and validation thermometers; Purchase, installation and validation of monitored and alarmed fridges and freezers for four sites.	Staffing records and documentation available at RBTS sites	
d) Mobile donation collection increasing the national blood supply and decreasing the reliance on donor incentives.	4 buses equipped as donation collection units; number of donations per capita; age profile of new donors; prevalence of infectious disease markers in donors	documentation available at RBTS sites	

Activities	Means	Assumptions
a) I: Training National QA Director and Quality Managers for compliance with Article 9 of Directive 2002/98/EC. .	a) I: 2 x 3-day workshops provided by external experts; overseas training for National QA Director and Quality Managers in Quality Departments with appropriate training facilities and expertise in EU Member States. This training will include all aspects of quality systems and quality management: document management, change control procedures and policies; quality assurance of all processes; quality control of reagents, material and products; product release and recall, etc.	Available facilities in EU Member States
a) II: Documentation: A complete description of all activities in the Romanian BTS, along with process maps and flows; A complete set of Standard Operating Procedures covering all activities in all centers; Change control and validation procedures and documentation in place; Additional documentation requirements to be specified under Article 29(h) of Directive 2002/98/EC in place.	a) II: External experts together with trained Quality Director & Quality managers	
b) I: Documentation. Develop user requirement specifications for national computer system.	b) I: Short and medium term external experts	
b) II: Training. Train key personnel in order to set up and use the national computer system.	b)II: Appointment of project team to undertake overseas visits to three sites to acquire detailed knowledge of available systems.; Medium term expert for workshops and product support.	International co-operation

b)III: Networked installation in key sites for evaluation and development of the system and the expertise in the RBTS.	b)III Purchase of IT equipment and software; External expert support.	
c) I: Documentation. Requirements for equipment and procedures for cold storage and transport, including validation and monitoring.	c) I: Short and medium term expert.	
c) II: Training. One week training course for key staff in the blood centres.	c)II: Short term expert.	
d)I: Installation of mobile facilities in key sites.	d)I Purchase, equipping and introduction into service of buses equipped as donation collection units with beds, assessment facilities, resting spaces etc.	
d)II: Assessment of impact of mobile collection on recruiting new donors in previously unvisited locations.	d)II Quantitative data collection and analysis by internal experts.	

Preconditions:
1. The MOH strengthens the organizational, consultative and financial support for the Romanian transfusion network
2. Efficient cooperation and coordination inside the national transfusion network
3. Commitment of the transfusion medicine specialists to sustain the reform

ANNEX 2: DETAILED TIME IMPLEMENTATION CHART FOR THE PROJECT

	2005												2006												2007											
Calendar months	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Activities																									-	-	-	-	-	-	-	-	-	-	-	-
A.1)																									-	-	-	-	-	-	-	-	-	-	-	--
a) Selection of a working group	**D**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**													-	-	-	-	-	-	-	-	-	-	-	-
b) Workshop on the existing legislation in the Member States and EC requirements, coordinated by experts in the field	**D**	**D**	**D**	**C**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
c) Study tour	**D**	**D**	**D**	**C**	**C**	**I**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
d) Elaboration of a draft of the new legislative framework submitted to the MoH for approval	-	-	-	-	-	-	**I**	**I**	**I**	**I**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A.2)																									-	-	-	-	-	-	-	-	-	-	-	-
a) Estabilishing of working groups for each domain of the transfusion chain	**D**	**D**	**D**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
b) Study tour	**D**	**D**	**D**	**C**	**C**	**I**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
c) Workshop on technical standards in transfusion	**D**	**D**	**D**	**C**	**C**	**I**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

medicine, coordinated by European experts in the field																																			
d) Elaboration of national technical standards in accordance with those set up by the EC Directive	**-**	**-**	**-**	**-**	**-**	**-**	**I**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
e) Training of BTCs managers on the new legislative framework approved by the MoH	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**C**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
B.1)																									**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
a) Developing a standard methodology and acquisition of software application	**D**	**D**	**D**	**D**	**C**	**C**	**C**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
b) Provision of IT equipment	**D**	**D**	**D**	**D**	**C**	**C**	**C**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
c)Training the medical personnel in charge with blood collection department to use the software application	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**D**	**C**	**C**	**I**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**

d) Gathering the BTCs donors' data to national level	-	-	-	-	-	-	-	-	-	-	-	-	I	I	I	I	I	I	I	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-
B.2)																									-	-	-	-	-	-	-	-	-	-	-
a) Selection of a working group	-	-	-	D	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
b) Elaboration of national guidelines in respect of the requirements of the Directive	-	-	-	-	-	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
c) Training the medical personnel from collection department	-	-	-	-	-	-	-	D	C	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
d) Provision of medical equipment for basic donors' medical examination	-	-	D	D	C	C	C	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
C.1)																									-	-	-	-	-	-	-	-	-	-	-
a) Selection of a working group	-	-	-	-	-	-	-	-	-	-	-	-	D	D	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
b) Acquisition of appropriate equipment certificated for blood transfusion services	-	-	-	-	-	-	D	D	C	C	C	I	I	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
c) Elaboration of procedures	-	-	-	-	-	-	-	-	-	-	-	-	-	-	I	I	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-
d) Monitoring of appropriate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	I	I	I	-	-	-	-	-	-	-	-	-	-	-

storage, transport and distribution parameters																																					
C.2)																										**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
a) Training for medical personnel in order to understand and respect the provision of the procedures	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**D**	**C**	**C**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
D.1)																										**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
a) Workshop With the participation of BTCs stakeholders and QA responsible	**D**	**D**	**D**	**C**	**C**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
b) Selection of working groups	**-**	**-**	**-**	**-**	**D**	**D**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
c) Elaboration of GMP, GLP, QAS, documentation and record Keeping regulation	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**D**	**D**	**D**	**D**	**D**	**D**	**D**	**D**	**I**	**I**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
d) Training for the medical personnel responsible for organizing and maintaining QS in each blood establishment	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**D**	**C**	**C**	**C**	**I**	**I**	**I**	**I**	**I**	**I**	**-**	**-**	**--**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**

e) Audit teams for monitoring the appliance of all mentioned regulations at local level(BTCs)	-	-	-	-	-	-	-	-	-	-	-	-	-	--	-	-	D	D	C	C	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-
E.1)																									-	-	-	-	-	-	-	-	-	-	-
a) Study tour	-	-	D	D	C	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
b) Workshop with the participation of transfusion and computer system experts	-	-	D	D	C	C	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
c) Acquisition of software application suitable with the previous used for donors data-base	-	-	-	-	D	D	C	C	C	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
d) Acquisition of IT equipment	-	-	-	-	D	D	C	C	C	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
e) Training for users										D	C	C	I	I	I	I	I	I	I	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-
E.2)																									-	-	-	-	-	-	-	-	-	-	-
a) Selection of a working group to elaborate the national guidelines	-	-	-	-	D	D	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
b) Training for clinical users	-	-	-	-	-	-	-	-	-	-	-	-	D	D	D	C	C	I	I	I	I	I	-	-	-	-	-	-	-	-	-	-	-	-	-

c) Printing and distribution of handbooks on clinical use of blood for clinical services use.	**-**	**-**	**-**	**-**	**-**	**-**	**D**	**D**	**C**	**C**	**I**	**I**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**

ANNEX 3: CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE

Title : Strengthening the Capacity of the Romanian Ministry of Health in order to comply with the EC Standards regarding the Transfusion Safety

DATE : 15.01.2004

	31/03/2005	30/06/2005	30/09/2005	31/12/2005	31/03/2006	310/06/2006	30/09/2006	31/12/2006	30/03/2007
Contract 1 : Technical Assistance									
CONTRACTED	50.000	150.000	200.000	200.000	300.000	300.000	-	-	-
DISBURSEMENT					200.000	400.000	600.000	900.000	1200.000
Contract 2 : Investment									
CONTRACTED	-	-	-	1.500.000	-	-	-	-	-
DISBURSEMENT	-	-	-	-	-	1.000.000	1.500.000	-	-

NB: 1. All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of the FM.

2. All disbursements must be completed within 36 months of signature of the FM.

ANNEX 4

NO FEASIBILITY STUDIES HAVE BEEN MADE.

ANNEX 5

LIST OF RELEVANT LAWS AND REGULATIONS

Legislation related to the project goal:

→ "The Law Regarding Blood Donation, therapeutic use of human blood and organization of transfusion in Romania", no. 4/Jan.1995

- Government Decision no.294/1995

→ MoH National Programme for Transfusion Hematology

→ Directive 2002/98/EC (Jan. 2003)

→ Council of Europe Guide to the preparation ,use and quality assurance of blood components

→ WHO Recommendations.

ANNEX 6

REFERENCE LIST OF RELEVANT STATEGIC PLANS AND STUDIES

MoH National Programme for Transfusion Hematology