1 BASIC INFORMATION

1.1 CRIS Number: 2008/020-406

1.2 Title: Implementation of Hospital Information System (HIS)

1.3 ELARG statistical code: 02.28

1.4 Location: Republic of Serbia

Implementing arrangements:

1.5 Contracting Authority: EC Delegation to the Republic of Serbia

1.6 Implementing Agency: EC Delegation to the Republic of Serbia

1.7 Beneficiary (including details of project manager):
Republic of Serbia, Ministry of Health, Nemanjina str.22-26, Belgrade.

The Project Manager is the Assistant Minister of Health.

A Steering Committee will meet regularly to provide continuous input on policy and technical matters throughout the Project.

Financing:

1.8 Overall cost: 7,500,000 EUR

1.9 EU contribution: 7,500,000 EUR

1.10 Final date for contracting: 3 years after the signature of the Financing Agreement

1.11 Final date for execution of contracts: 5 years after the signature of the Financing Agreement

1.12 Final date for disbursements: 6 years after the signature of the Financing Agreement

2 OVERALL OBJECTIVE AND PROJECT PURPOSE

2.1 Overall Objective:
To improve the efficiency and quality of health care delivery in Serbia through further development and implementation of a standardised and sustainable Hospital Information System at secondary/tertiary level of health care, which will contribute to the establishment of an integrated national health information system.

2.2 Project purpose:
Continue the improvement of the Electronic Health Record developed through the CARDS 2004 project “Development of Health Information System for Basic Health and Pharmaceutical Services Republic of Serbia” and the Ministry of Health “Serbia Health Project” by integrating data delivered by healthcare institutions. Upgrade and implement a
customized hospital information system in 10 hospitals, covering the needs of 30 % of the population of Serbia.

2.3 Link with AP/NPAA / EP/ SAA

In the Council Decision on the principles, priorities and conditions contained in the European Partnership with Serbia including Kosovo as defined by United Nations Security Council Resolution 1244 of June 1999 and repealing Decision 2006/56/EC, it is stated:

European Standards

Employment and Social Policies

Develop adequate administrative structures and capacity in the field of health protection.

Obtaining data by implementing hospital information system will improve hospital management as basis for evidence-based decision making.

2.4 Link with MIPD¹

This project will ensure the persistence of stronger leadership and the handling of greater responsibilities in the reform process of health care financing, and will also develop linkages with the national investment programming.

The project will introduce basic reform of data follow-up at health institution level, developed through the relevant 2004 CARDS programme.

The Executive Summary of the 2007-2009 MIPD for the Republic of Serbia cites:

2.2.2 Socio-economic Requirements

2.2.2.1 Main priorities and objectives

Improve regulatory and management capabilities of health financing institutions and health care authorities, institutions and programmes.

2.2.2.2 Expected results and time frame

Administrative and operational capacities improved and improved quality and efficiency of services which are provided in the health care system, especially in conditions of limited resources. Preventive health services improved.

2.2.2.3 Programmes to be implemented in pursuit of these objectives

In the annual programmes 2007-2009 assistance may be provided to support implementation of continuous quality improvement of health institutions.

Quality improvement is a necessary part of health system reforms which will enhance patient and health care provider satisfaction. Patient information obtained through the HIS, and the further development of electronic health records (EHR), serve as a foundation for the planning of human resources in health institutions as well as for the improvement of financial management. The proposed project will build on the previous EU support that was given through the CARDS programme. Development and implementation of a hospital information system is one of the important steps leading to improvements in health care quality, efficiency and equal access.

¹ Multi-Annual Indicative Planning Document
2.5 Link with National Development Plan (where applicable) n/a

2.6 Link with national / sectoral plans

NIP (National Investment Plan) 2006-2008: Introduction of IT network infrastructure in 162 primary health centres (part of the reconstruction of primary health centres in Serbia, total value: 60,000,000 Euro)

The Health Care Law of the Ministry of Health, 7th Integrated Health Care Information System, Article 74 reads: “In order to plan and efficiently manage the health care system, as well as collect and process the data concerning public health and the functioning of health care services, i.e. collect and process information pertaining to health care, the integrated health care information system (IHIS) shall be organised and developed in Serbia.”

3 DESCRIPTION OF PROJECT

3.1 Background and justification:

The proposed project shall build on the results achieved through the 2004 CARDS EHR project, by rolling-out the health information system to secondary and tertiary level health care institutions, targeting 10 hospitals (in addition to the four that have an already developed HIS through the SHP project) that will then be integrated with the national HIS. This step is vital to the development of a universal health information system as the data to be incorporated into the system through the secondary and tertiary level of health care will comprise the basis for EHR information which will then be accessible at all levels of health care institutions.

The present Serbian health care system relies primarily on obsolete paper-based administrative methods of record-keeping, management and provision of support to health care delivery. Initial steps have been taken to develop and implement more efficient and effective information systems that will provide for the development of evidence-based health policies as well as improved overall health system management and more cost-effective and patient-centred health care delivery. By establishing an IHIS (Integrated Health Information System), the MoH is making the necessary commitment that will lead to improvements health care quality, efficiency and access, while also moving the health care system closer to harmonisation with relevant EU standards.

Components of the Serbian IHIS are being realised through a combination of several ongoing projects and others which are currently in the pipeline. All of these projects are connected in functionality, but are being implemented in a variety of different locations and a number of institutions (see Section 3.7). The central components of the IHIS will in part be hosted at the National Institute of Public Health "Dr Milan Jovanovic - Batut" (IPH) and the Health Insurance Fund (HIF). The regional components of the IHIS will be implemented at the regional health care institutions at primary, secondary and tertiary level and in pharmacies. The proposed project focuses on developing a hospital information system (HIS) and thus targets secondary and tertiary health care institutions.

The Central Information Services (CIS) of the “Serbia Health Project” developed a database of health resources, nomenclatures, classifications, registers, etc. to be implemented as web portal application.

The HIF central component, database of insurees and a secured, private Wide Area Network (WAN) will provide the infrastructure for a database of insurees and will be used in the proposed project.
The MoH “Serbia Health Project”, which is developing and implementing the HIS for four regional hospitals\(^2\) has developed and tested the models of HIS (HIS1 and HIS2) that will be instrumental to the software upgrades that form the cornerstone of the proposed project.

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

See 3.1, 3.6 section

Expenditure for financing of the HIS is built into the overall budget for health care. Having that in mind, it is important to consider what is the amount of those resources, what the dynamic of its use is, and most importantly, what benefits and savings this long-term investment will bring.

Building upon the achievements to date through the CARDS and other projects, the ICT\(^3\) now needs to be standardised, taking into account broad stakeholder needs and reflecting a clear vision so that expectations for long-term results are realistic. In that sense, HIS is a means by which to improve efficiency of access to information, mutual communication, better quality assurance and better planning. HIS will optimise the results achieved through the CARDS project while enabling the standardisation of ICT systems within secondary and tertiary health care institutions. HIS will at the same time allow for internal customisation of each of these systems, according to the specific needs of each hospital. Overall, the HIS will be integrated with the health care information system, providing for the greater access and transfer of EHR at all levels of health care.

More concretely, the HIS will impact upon the following:

- Health information which will help health care employees make clinical decisions, including the universal implementation of good practice guidelines, knowledge transfer and sharing professional literature.
- Use of data in supporting public health functions, planning, monitoring and evaluating health care services, including management and planning in human resources, financing and allocation of resources, health care services quality monitoring, and monitoring the rational spending of resources.
- Use of data in supporting the development and application of decisions concerning the comprehensive health care of individuals, groups with special needs and the entire population.
- Use of data in health research.
- Information on the factors that determine the overall state of an individual's health, based on evidence. Evidence Based Medicine aims to apply evidence gained from the scientific method of medical practice and to assess the quality of evidence relevant to the risks and benefits of treatments.
- Easier compliance with international obligations through adoption of European standards and initiatives.

Besides fulfilling basic strategic principles, investments in HIS, with rational management, can create measurable, significant economic benefits in the sense of assuring long-term savings and improving the sustainability of health care financing.

Results of the proposed HIS Implementation for 10 hospitals project will include the development of a financing model for HIS, that is the initial budget for the introduction of the HIS, plus an annual budget, from other sources (MoH, HIF, hospital, municipality, etc.), for its proper maintenance providing HIS sustainability.

---

\(^2\) The regional hospitals of Kraljevo, Valjevo, Vranje and Zrenjanin.

\(^3\) Information and communication technology
Functional sustainability will be achieved through the roll-out of those applications. It does
not however mean that the roll-out will be free-of-charge, as it requires additional
infrastructure (hardware, LAN), software adaptations for existing hospitals, implementation
and maintenance. Also, the network of hospitals with standardised HIS will be a very
important component of an integrated ICT of the health sector. So, capacity to absorb larger,
future sources of financing is also expected to result from HIS project implementation as the
level of necessary skills should considerably increase following project completion.

Concerning cross-border co-operation, the HIS, when harmonised with EU and international
standards, using a standardised minimal data set and standardised format for exchange, will
enable the exchange of medical data (interoperability) with other information systems existing
elsewhere. The proposed project will assist to attain epidemiological surveillance
(implementation of International Health Regulations).

Evidence-based decision making and health management will be strongly supported through
the implementation of this project.

3.3 Results and measurable indicators

3.3.1 Result 1: HIS software upgraded and integrated in the already developed existing
software according to the adopted standards.

Measurable indicators for reviewing progress include:
- HIS compliance improved with defined standard requirements
- HIS Improved and tested in ten hospitals
- Equipment procured and installed in the 10 targeted hospitals 16 months after contracting

3.3.2 Result 2: Hospital staff capacity built according to best EU practice to use
and maintain the HIS.

Measurable indicator for reviewing progress:
- 75% hospital staff in targeted hospitals trained and operational by the end of 2011
- 75% hospital linked and integrated with the electronic health record (CARDS 2004
project)

3.4 Activities:

3.4.1 Result 1:
Activity 1: To upgrade and integrate HIS software with the existing, already developed
software, in accordance with the adopted standards.

Activity 1.1: Procurement and installation of additional ICT equipment for the
implementation of this project

Activity 1.2: Customisation of HIS for each hospital

Activity 1.3: Testing of HIS for each hospital

3.4.2 Result 2:
Activity 2: Capacity building for hospital staff for HIS usage and maintenance in accordance
with best EU practices

Activity 2.1: Training of ICT staff in 10 hospitals to maintain HIS at the hospital level.
**Activity 2.2:** Training for end-users (doctors, nurses, pharmacists, hospital management and auxiliary staff) to use the HIS in 10 hospitals.
3.5 Conditionality and sequencing:

**Conditionality**

The required legislation is upgraded (the Law on Medical Records). A National Clearing House Unit is established within the National Institute for Public Health in accordance with the Law.

**Sequencing**

<table>
<thead>
<tr>
<th>Contracting Arrangement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The project will have two contracts as follows:</td>
</tr>
<tr>
<td>1. A service contract to upgrade and implement the HIS software and to train the hospital staff in its use.</td>
</tr>
<tr>
<td>2. A supplies contract for the procurement of IT equipment</td>
</tr>
</tbody>
</table>

3.6 Linked activities

**Development of a Health Information System for Basic Health and Pharmaceutical Services in the Republic of Serbia, alias the EHR (Electronic Health Record),** is an EU-funded 2004 CARDS project aiming to develop a clearing-house database of the most important health information for each citizen. The EHR is a collection of information (in electronic form) related to the health of an individual patient, spanning a continuous period of time “from cradle to grave”. The data necessary for EHRs are collected by health care professionals, at the place where health care services are delivered, using modern information and communication technologies. The Clearing-house software provided by the CARDS project cannot be fully operational without the data that obtained through the hospital information system. The proposed project would thus help create the necessary conditions to implement the EHR effectively.

The MoH **Serbia Health Project**, which is developing and implementing an HIS for four regional hospitals and is funded mainly through a World Bank loan, has developed and tested two models of an HIS (HIS1 and HIS2) instrumental to the software upgrades forming the cornerstone of the proposed project. The SHP has also supported the development of databases and the WAN through an HIF project, as well as the establishment of resource databases. It is important to note that the SHP is actually a MoH project that has received funding through World Bank credit and a project that will continue as resources allow. The World Bank loan has supported the SHP from 2003 and is expected to come to completion in August 2008.

3.7 Lessons learned

Through the proposed project no new software will be developed, but already developed software and structures will be upgraded and implemented, thereby avoiding the risk of HIS implementation failure.
### 4. Indicative Budget (amounts in EUR)

<table>
<thead>
<tr>
<th>ACTIVITIES</th>
<th>TOTAL EXP. RE</th>
<th>IPA COMMUNITY CONTRIBUTION</th>
<th>NATIONAL CONTRIBUTION</th>
<th>PRIVATE CONTRIBUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IB (1)</td>
<td>INV (1)</td>
<td>EUR (a)=(b)+(c)+(d)</td>
<td>EUR (b)</td>
</tr>
<tr>
<td>Activity 1</td>
<td></td>
<td>x</td>
<td>6.000.000</td>
<td>6.000.000</td>
</tr>
<tr>
<td>contract 1.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity 2</td>
<td></td>
<td>x</td>
<td>1.500.000</td>
<td>1.500.000</td>
</tr>
<tr>
<td>contract 2.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>……</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL IB</td>
<td>1.500.000</td>
<td></td>
<td>1.500.000</td>
<td></td>
</tr>
<tr>
<td>TOTAL INV</td>
<td>6.000.000</td>
<td></td>
<td>6.000.000</td>
<td></td>
</tr>
<tr>
<td>TOTAL PROJECT</td>
<td>7.500.000</td>
<td></td>
<td>7.500.000</td>
<td></td>
</tr>
</tbody>
</table>

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

Amounts net of VAT
(1) In the Activity row use "X" to identify whether IB or INV; (2) Expressed in % of the Total Expenditure (column (a))
5. INDICATIVE IMPLEMENTATION SCHEDULE

<table>
<thead>
<tr>
<th>Contracts</th>
<th>Start of Tendering</th>
<th>Signature of contract</th>
<th>Project Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract 1.1</td>
<td>T + 1Q</td>
<td>T + 4Q</td>
<td>T + 16Q</td>
</tr>
<tr>
<td>Contract 1.2</td>
<td>T + 2Q</td>
<td>T + 6Q</td>
<td>T + 16Q</td>
</tr>
</tbody>
</table>

6. CROSS-CUTTING ISSUES

Equal Opportunity
Throughout HIS implementation there will be no discrimination on the grounds of health status, race, gender, sexual orientation, mother tongue, religion, political or other opinion, national or social origin, birth or other status. Equal opportunities for all will be ensured during project implementation. Training of hospital staff, as part of the project, will aim at providing equal opportunities for women.

Environment
HIS enables access to accurate and timely data, which could be of use to environmental protection, particularly medical waste and computing equipment. The project will additionally help targeted hospitals reduce their consumption of paper for administrative purposes.

Minority and vulnerable groups
HIS is a patient-oriented system which aims to ensure fair access to health care services for men and women, ethnic minorities and people with special needs.
### LOGFRAME PLANNING MATRIX FOR Project Fiche

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project Fiche</th>
<th>Implementation of Hospital Information System (HIS)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contracting period expires 3 years after the signature of the Financing Agreement</td>
<td>Disbursement period expires 6 years after the signature of the Financing Agreement</td>
</tr>
<tr>
<td></td>
<td>Total budget : €7,500,000</td>
<td>IPA budget: €7,500,000</td>
</tr>
</tbody>
</table>

#### Overall objective

**To improve the efficiency and quality of health care delivery in Serbia through the development and implementation of a standardized and sustainable HIS which will contribute to integrated national health information system**

- Improved health care system
- Established qualitative and standardized HIS
- Documents which define policies
- Project reports
- MoH reports
- HIF report

#### Project purpose

**Continue the improvement of the Electronic Health Record developed through the CARDS 2004 project “Development of Health Information**

- Improved satisfaction of population, patients and employees with health care system
- Improved hospital
- Final project report
- MoH internal reports
- Waiting list for health care activities
- Consistent approach to health care policy and determination of the Government to undertake the reform
System for Basic Health and Pharmaceutical Services Republic of Serbia” and the Ministry of Health “Serbia Health Project” by integrating data delivered by healthcare institutions. Upgrade and implement a customized hospital information system in 10 hospitals, covering the needs of 30% of the population of Serbia.

<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>management through available and reliable data</td>
<td></td>
<td>of the health care system</td>
</tr>
<tr>
<td></td>
<td>• Shorter average administrative time</td>
<td></td>
<td>• Readiness of the MoH and HIF to integrate approach for planning and management of key processes in performing of common strategies</td>
</tr>
<tr>
<td></td>
<td>• Improved quality of health care</td>
<td></td>
<td>• Collaboration between the MoH with other institutions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Readiness of health care institutions for change implementation</td>
</tr>
</tbody>
</table>
**Result 1:** HIS software upgraded and integrated in the existing software according to adopted standards.

- HIS compliance improved with defined standard requirements
- Improved and tested HIS in ten hospitals
- Procured and installed equipment in all of the 10 targeted hospitals by 16 months after contracting
- 75% hospital staff in targeted hospitals trained and operating by the end of 2011
- 75% hospital linked and integrated with EHR (CARDS 2004 project)

**Technical Responsiveness Checklist**

- Project documentation and source code of improved HIS
- Acceptance statement of equipment installation and test report
- Acceptance statement and software test
- Training reports, evaluation sheets signed by trainers and trainees.

**Result 2:** Hospital staff capacity built according to best EU practice to use and maintain the HIS.

- Hospital staff capacity linked and integrated with EHR

**Activities**

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Costs</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| **Activity 1:** To upgrade and integrate HIS software in existing already developed software according to adopted standards. | Continue the improvement of the Electronic Health Record developed through the CARDS 2004 project “Development of Health Information System for Basic Health and Pharmaceutical Services Republic of Serbia” and the Ministry of Health “Serbia Health Project” by integrating data delivered by healthcare institutions. Upgrade and implement a customized covering the needs of 30 % of the population of Serbia |                                                                                                   | Collaboration of the MoH with other institutions
| **Activity 1.1:** Procurement and installation additionally needed of ICT equipment for the implementation of this project |                                                                                                   |                                                                                                   | Readiness of MoH and HIF to provide sustainability of HIS
<p>| <strong>Activity 1.2:</strong> Customisation of HIS for each hospital                    |                                                                                                   |                                                                                                   | readiness of health care institutions for HIS implementation |</p>
<table>
<thead>
<tr>
<th>Activity 1.3: Testing of HIS for each hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital information system in 10 hospitals</td>
</tr>
</tbody>
</table>

**Activity 2:** Capacity building for hospital staff according to best EU practice for using and maintaining the HIS

**Activity 2.1:** Training of ICT staff in 10 hospitals to maintain HIS at the hospital level.

**Activity 2.2:** Training for end-users (doctors, nurses, pharmacists, hospital management and auxiliary staff) to use the HIS in 10 hospitals.

- Concern of employees and end-users for implementation of HIS
- Motivation of the employees for education
## ANNEX II: AMOUNTS CONTRACTED AND DISBURSED PER QUARTER OVER THE DURATION OF THE PROJECT (IN €)

<table>
<thead>
<tr>
<th>Contracted</th>
<th>Q4</th>
<th>Q6</th>
<th>Q8</th>
<th>Q10</th>
<th>Q12</th>
<th>Q14</th>
<th>Q16</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract 1.1</td>
<td>1,500,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,500,000</td>
</tr>
<tr>
<td>Contract 1.2</td>
<td></td>
<td>6,000,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,000,000</td>
</tr>
<tr>
<td><strong>Cumulated</strong></td>
<td><strong>1,500,000</strong></td>
<td><strong>7,500,000</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>7,500,000</strong></td>
</tr>
<tr>
<td>Disbursed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 1.1</td>
<td>150,000</td>
<td>225,000</td>
<td>225,000</td>
<td>225,000</td>
<td>225,000</td>
<td>225,000</td>
<td>225,000</td>
<td><strong>1,500,000</strong></td>
</tr>
<tr>
<td>Contract 1.2</td>
<td>2,700,000</td>
<td></td>
<td></td>
<td></td>
<td>2,700,000</td>
<td></td>
<td>600,000</td>
<td><strong>6,000,000</strong></td>
</tr>
<tr>
<td><strong>Cumulated</strong></td>
<td><strong>150,000</strong></td>
<td><strong>3,075,000</strong></td>
<td><strong>3,300,000</strong></td>
<td><strong>3,525,000</strong></td>
<td><strong>6,450,000</strong></td>
<td><strong>6,675,000</strong></td>
<td><strong>7,500,000</strong></td>
<td><strong>7,500,000</strong></td>
</tr>
</tbody>
</table>
ANNEX III: INSTITUTIONAL FRAMEWORK

The Ministry of Health of the Republic of Serbia is in charge of the implementation and monitoring of this project. The work, mandate and authorisations of the Ministry are regulated by the Law on Ministries (adopted on 15 May, 2007 (Official Gazette of the Republic of Serbia, No. 48/07) – i.e. Article 21.

The Ministry consists of the following sectors:

1. Sector for the Organisation of Health Services and Health Inspection
2. Sanitary Surveillance Sector
3. Sector for Programmes in Healthcare and Public Health
4. Sector for Medicines and medical devices
5. Sector for Health Insurance and Financing
6. Sector for European Integrations and International Relations
ANNEX IV: REFERENCE TO LAWS, REGULATIONS AND STRATEGIC DOCUMENTS:

Health Care Law (Official Gazette RS 107/05)
Health Insurance Law (Official Gazette RS 107/05)
Law on documentation in health care (Official Gazette RS 44/91, 53/93, 67/93, 48/94);
Regulations on medical documentation, data acquisition and reporting (Official Gazette SRS 40/81)
Instructions on unique methodology and statistical standards for data acquisition and reporting in health care (Official Gazette SRS 54/81)
Regulations on forms and procedures for managing patient registries for certain diseases (Official Gazette SRS 2/80)
Regulations on procedures for reporting contagious diseases (Official Gazette SRS 11/79)
### ANNEX V: DETAILS PER EU FUNDED CONTRACT

<table>
<thead>
<tr>
<th>Activity</th>
<th>Budget (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Package I</td>
<td></td>
</tr>
<tr>
<td>1. purchase of equipment</td>
<td>6,000,000</td>
</tr>
<tr>
<td>Work Package II</td>
<td></td>
</tr>
<tr>
<td>2. technical assistance</td>
<td>1,500,000</td>
</tr>
</tbody>
</table>

**Grand total:** 7,500,000