1.1 **CRIS Number**: 2006/018-180.01-01  **Twinning No**: PL/06/IB/SO/01/TL

1.2 **Title**: Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare

1.3 **Sector**: Public administration

1.4 **Location**: Poland, Ministry of Health / National Centre for Health Information Systems, Warsaw

2 Objectives

2.1 Overall objectives
Improving health system effectiveness and increasing healthcare quality in Poland. Endeavour to achieve synergy between national health systems in Europe.

2.2 Project Purpose
Implementation and control of application of European standards for data communications systems in healthcare.

Obtaining the eHealth interoperability at the national and European levels.
Increasing mobility of patients within internal market of health services.

2.3 Justification
In the Comprehensive Monitoring Report on Poland’s Preparations for Membership (CMR), chapter 13 *Social Policy and Employment*, section on public health says that “it is necessary to undertake further efforts particularly in regards to the system of crisis management, systematic monitoring, better data analysis, laboratory possibilities, providing confidentiality of patients’ personal data and immediate response”.

Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare enhances the capability of responding rapidly and in a co-ordinated fashion to health threats in European countries.

Data analysis will not be possible without efficient medical information system providing the data. Hence, it is necessary to provide coherence of data communications systems in healthcare. Because of this, it is necessary to intensify the actions connected with implementation of European standards in these systems because such activity guarantees coherence of action.

According to the CMR recommendation - expressing concern over the free movement of services, the project will have substantial impact on the international and transborder sharing of health services.
Harmonised rules concerning personal data protection and certain information society services will also be respected by the international standards of information technology concerning codes of practice for information security management.

3. Description

3.1 Background and justification

In its negotiation standpoint as for the free flow of goods (appendix 1) in part 10 Horizontal and Procedure Issues, Poland “acknowledged the fundamental regulating character of the acquis regarding the horizontal and procedure issues. It particularly applies to the Council Decision 87/95/EEC (the decision of European Communities Council of December 22, 1986 as for the standardisation in information and telecommunication technologies), as well as the Council decision 95/486/EC (information exchange between IDA administrations)”.

The project is to enable supervision of exercising of Decision 87/95/EEC which in article 5 says that “taking into consideration the differences between existing internal procedures, the member states take all necessary action to provide that the following standards have been included”:
- European standards and temporary European standards
- International standards (if they were ratified in a country being a party of the contract) in public bids regarding information technologies so that the standards constitute basis for information and data exchange to provide interoperability of the systems.

Necessity of realisation of the above results also from European Union Directives for the public bids.


3.2 Linked activities

The project is connected with actions taken by the Ministry of Internal Affairs and Administration related with implementing the minimum requirements for data communications systems.

National Centre for Health Information Systems is responsible for preparation of the law “Medical Information”, that will be complementary to the “Law on the informatisation of subjects realizing public tasks”. Implementation of standards of machine readable and machine processable formats is fundamental to the sharing of administrative data between healthcare and insurance systems. It concerns attempts of introducing common identifier and provides the unique opportunity of interoperability of healthcare systems.

The project composes the essential complement of these activities.
3.3 Results

Contract 1.

- a draft of regulations regarding the control of standards observation will be prepared
- a draft of regulation regarding the preparation of data communications systems in healthcare will be made,
- good practice guidelines for introduction the standards of the administrative data and medical data into healthcare developed,
- training of the providers and users of medical information systems in the field of standardization of the healthcare-related data collecting and managing performed,
- approval tests to investigate the compliance of systems with European standards prepared,
- a website promoting standardisation of data communications systems in healthcare and inspiring the preparation of the future standards built

Contract 2.

- all standards indicated by WHO and CEN/ISS, crucial for the implementation of the technical platform for the open source and interoperable eHealth solutions across Community, adapted for the purposes of legislation and training,
- handbooks with guidelines for end users regarding standards application prepared,
- 16 trainers trained in standardization in data communications systems in healthcare.

3.4 Activities

Assistance will comprise two contracts

3.4.1 Contract 1. Twinning light contract on the consolidation of standard implementation system: 0.151 M€ (duration – 6 months)

- preparing an outline of regulations regarding the development of standard-abiding data communications systems in healthcare which are in compliance with the standards
- preparing an outline of legal procedures providing framework for controlling application of standards in data communications systems in healthcare.
- development of good practice guidelines for introduction the standards of the administrative data and medical data into healthcare
- interactive training of the providers and users of medical information systems in the field of standardization of the healthcare-related data collecting and managing,
- approximately 3 study trips of Polish specialists to make acquainted with the introduction of medical information standards into healthcare and telemedicine as well
- organizing seminars, workshops and field visits for computer specialists in the central healthcare institutions – approx. 50 participants
- preparing handbooks with guidelines for end users regarding standards application
- preparing approval tests to investigate the compliance of systems interface as for European standards compliance
Handbook costs = approx. 0.025 M€

Contract realisation will require a Project Leader and 4 short-term experts (STEs).

Project Leader is responsible for:
- co-ordination of preparing principles of law regulation for the applications of standards
- selection of the set of standards and supervision of their adaptation to the current and future needs for interoperable e-Health European systems and to the needs that are relevant to the training and legislation processes as well
- supervision of training courses and other activities.

The Project Leader profile:
- has worked in standardization in healthcare for at least 10 years;
- has the experience in e-Health applications
- preferably previous/actual activities in the co-operation with CEN/ISO or national standardization bodies
- preferably good computer literacy

STEs are responsible for:
- preparation of outlines of legal regulations of the implementations of the standards in healthcare
- preparation and organizing training courses, seminars and workshops
- active support at all stages of the project

The short-term expert profile:
- competence in legal aspects of standardisation in healthcare is required
- civil servants from a MS
- a minimum of 10 years experience and knowledge based on practical skills in information technology in healthcare, especially in the EU member states
- experience in Eastern European countries will be an asset
- experience in the cooperation with TC 251 CEN will be an asset
- good command of spoken and written English

They are expected to ensure activities planned in the framework and provide training for Polish specialists.

STEs (experienced) costs approx. 4 STEs x 3 Visits x 8 Days = approx. 0.109 M€

Seminars and workshops: approx. 5 x 5 days, approx. 0.009 M€
Study visits: 3 study visits to EU MSs x 3 participants each x 5 days = approx. 0.008 M€
The beneficiary will enable the experts to possess basic knowledge on the project background, providing information on present law regulations in Poland, characteristics of the needs in the scope of implementation of European Union law regulations. The beneficiary will coordinate participation of employees of the National Centre for Health Information Systems in the expert missions as well as by providing necessary equipment for the missions.

3.4.2 Contract 2. Technical assistance: 0.330 M€
- accomplishment of the analysis of the importance of the WHO / CEN/ISSS standards for the e-Health legislation across the Community and selection the set of standards that are of crucial value for interoperability
- preparation and adaptation for the legislation and training purposes of the selected important standards indicated by CEN/ISSS regarding data communications technology in healthcare. The sphere of activities should take into account European recommendations and Polish experiences in implementation of the telematic standards to the healthcare.
(Classified list of existing standards and work in progress comprises approx. 200 positions with approx. 100 pages each).
The costs of the analysis, adaptation and verification = approx. 0.311 M€
- building a website promoting standardisation of data communications systems in healthcare. The site will provide continually updated information and guidelines for users and designers of data communications systems in healthcare.
Website costs will be financed nationally.
- conducting advanced trainings for trainers in standardisation in data communications systems in healthcare – approx. 16 trainers - organising seminars, workshop

Seminars and trainings for healthcare managers, the staff of medical care units that is responsible for data flow and management, health practitioners – approx. 300 participants approx. 5 seminars x 5 days, approx. 0.009 M€

Assistance from a short-term expert in standardisation in informatics in healthcare is required. Assistance from a short-term expert in organizing comprehensive trainings in designing standards and introducing them into telemedical systems.

The knowledge of telematic standards in medicine is very specialized one. That is why the consultants are obliged to be acquainted with medical and informatic issues as well. Therefore, their profiles and tasks should be the same.

3.5 Lessons learned:
Experience in realisation of the governmental projects of standardization has been gathered for 6 years. The organisation itself noted carefully the lessons learned, as well. It is important to ensure that the project is properly managed throughout its lifecycle. From the beneficiaries' side this will be done by the appointment of a project leaders and a project team for each component, who will work in close conjunction with the Short Term Experts. The top management of the beneficiaries’ institutions have to be deeply involved and to support the project realization.
4. Institutional framework

4.1
The project will be co-ordinated by a unit supervised by Ministry of Health – National Centre for Health Information Systems, which is the main beneficiary of the project. The purpose of NCHIS is the development of information systems enabling activities of optimizing the health care financing (Health Ministry Official Diary 28.04.2004).

Programme operation is planned so as to provide its regulating and integrating character for data communications systems in healthcare. The tight cooperation with the Ministry of Internal Affairs and Administration is assumed as concerns the introduction of common identifier. The following institutions will be involved at the local level:

- founding bodies of the Independent Public Healthcare Units (Samodzielne Publiczne ZOZ). The unit responsible for the realisation and coordination of the project is the Centre for Informational Systems in Healthcare (Centrum Systemów Informacyjnych Ochrony Zdrowia (CSIOZ)), located at: Warszawa 02-326, al. Jerozolimskie 155, tel. (+4822) 824-2727, fax. (+4822) 824-2737.

- 4.2 N/A

- 4.3 N/A

- 4.4 N/A

5. Detailed budget (MEUR)

<table>
<thead>
<tr>
<th>Transition Support Facility</th>
<th>Co-financing</th>
<th>Total cost (TF+co-financing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
</tr>
<tr>
<td>Contract 1 Twinning Light</td>
<td>0.151</td>
<td>0.151</td>
</tr>
<tr>
<td>Contract 2 Technical Assistance</td>
<td>0.330</td>
<td>0.330</td>
</tr>
<tr>
<td>Total</td>
<td>0.481</td>
<td>0.481</td>
</tr>
</tbody>
</table>

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

(**) private funds, FIs loans to private entities

* In cases of co-financing only

The co-financing funds for the project implementation will be available.

The amounts for national co-financing indicated in the table correspond to cash co-financing,
unless otherwise stated. Contributions from the Polish administration for effective implementation of the twinning light/TA may be further detailed in the twinning contract/Terms of references. Unless otherwise indicated joint co-financing is provided. VAT does not constitute eligible expenditure except where it is genuinely and definitely borne by the final beneficiary. VAT which is considered recoverable, by whatever means, cannot be considered eligible, even if it is not actually recovered by the final beneficiary or individual recipient.

In case of parallel co-financing, the following activities will be financed from the parallel co-financing provision in the budget table: cost of the administration (equipped board rooms, secretariat support, photocopiers, catering and running costs to ensure sustainability), the national experts contribution to the project, accommodation and travel costs of the STEs, study visits costs (travel costs etc.).

According to the joint financing procedure, the total cost of contract 2 (0.358MEUR) will be financed with both Transition Facility funds and Polish funds, in proportions corresponding with contributions declared in the budget table.
6. Implementation arrangements:
There will be a Project Steering Committee (PSC) established in order to speed up the implementation process of the given project components in the first months after Financial Decision for Transition Facility 2006 is taken. The structure of the Committee will be working as an advisory and monitoring body until particular components are contracted and thus where appropriate may be replaced by the Twinning Steering Committee as well as Steering Committees for TA component independently.

The participants of the Project Steering Committee will be representatives of the following institutions: PAO, NAC, CFCU and beneficiary (SPO, contact person as indicated in the fiche and representative from Office for Foreign Aid Programmes in Heath Care). It is also recommended to invite representatives of NAO services while the issues of financial management flow are to be comprehensibly discussed. The Project Steering Committee will meet every quarter starting from the date of signing the Financial Decision and will concentrate on discussing the problem occurred at the beginning phase of project implementation as well as on defining possible solutions and corrective measures. The PAO representative will organise and chair the PSC meetings.

6.1 Implementing Agency

PAO – Tadeusz Kozek Undersecretary of State in the Office of the Committee for European Integration (UKIE). Aleje Ujazdowskie 9, 00-918 Warszawa; phone +48 (22) 455-52-41

The CFCU is responsible for handling tendering, contracting and payments of contracts on behalf of the Ministry of Health which itself will be responsible for preparing projects and managing their technical implementation.

6.2 Twinning

Project leader:
Leszek Sikorski MD, – National Centre for Health Information Systems, Director, Warszawa 02-326, Al. Jerozolimskie 155, tel. (+4822) 597 09 27, fax (+4822) 597 09 37

Experts – consultations in issues established by beneficient.
Benficiary - National Centre for Health Information Systems

SPO
Waldemar Skawiński MD, PhD – National Centre for Health Information Systems, Deputy Director, Warszawa 02-326, Al. Jerozolimskie 155, tel. (+4822) 597 09 27, fax (+4822) 597 09 37

Contact person:
Andrzej Skubalski - National Centre for Health Information Systems
Warszawa 02-326, Al. Jerozolimskie 155, tel. (+4822) 597 09 27, fax (+4822) 597 09 37

Administrative Office: Department for Institution Building Programmes, Office of the
6.3 Non-standard aspects
N/A

6.4 Contracts

1. Contract 1 Twinning Light 0.168M€ gross value (0.151M€ TF + 0.017M€ co-financing) parallel co-financing
2. Contract 2 TA 0.358 M€ gross value (0.330M€ + 0.028M€ co-financing) joint co-financing

7. Implementation schedule

7.1 Twinning Light:
7.1.1 Commencement of contracting process: 4th quarter of 2006
7.1.2. Start of project implementation (signature of contract): 2nd quarter of 2007
7.1.3. Project completion: 4th quarter of 2007

7.2 Technical assistance:
7.1.1 Commencement of contracting process: 4th quarter of 2006
7.1.2. Start of project implementation (signature of contract): 3rd quarter of 2007
7.1.3. Project completion: 4th quarter of 2007

8. Sustainability

CSIOZ has planned adequate staff and financial resources to maintain the realisation of coordinating, controlling and implementing assignments as for implementation of European standards in data communications in healthcare.

9. Conditionalities and Sequencing
9.1 Conditionalities
Missing of essential obstacles for beginnings of project
9.2. Sequencing:
- Start of tendering – IV q. 2006;
- Start of project activities – II Q 2007;
- Implementation of the project in co-operation with the Consultant, twinning partner and beneficiary institutions – III/IV Q 2007
<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving health system effectiveness and increasing healthcare quality in Poland.</td>
<td>1. Comparison in perspective of subsequent years of amounts expended and number of projects conducted in Poland by subsidiaries of companies from other EU states and by Polish companies in other EU states</td>
<td>The questionnaire research and department statistics (Ministry of Health, Central Statistical Office, Ministry of Internal Affairs and Administration and healthcare units)</td>
</tr>
<tr>
<td>Endeavour to achieve synergy between national health systems in Europe.</td>
<td>2. Comparison in quantity and amount in subsequent years of purchased medical equipment (according to its types, e.g. computer tomographs) conforming with European standards for information technologies in healthcare</td>
<td>Professional staff involved in the project.</td>
</tr>
<tr>
<td></td>
<td>3. Investigation of formats of data exchange in existing and being implemented data communications systems. Evaluation of the number of institutions with implemented standards for information exchange</td>
<td></td>
</tr>
</tbody>
</table>

**PROGRAMME NAME AND NUMBER:**
Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare

**LOGFRAME PLANNING MATRIX FOR**
Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare

**Contracting period expires:** IV Quarter, 2008
**Disbursement period expires:** IV Q 2009

**Total Budget:** 0.526 MEUR
**TF budget:** 0.481 MEUR
4. Investigation of formats of data exchange in existing and being implemented data communications systems. Evaluation of the number of institutions with implemented standards for information exchange.

5. Investigation of specifications of relevant order conditions as for meeting the requirements in application of European and Polish standards (art. 30 of the act for Law of Public Tenders).

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of verification</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| - Implementation and control of European standards for data communications systems in healthcare.  
  - Obtaining the eHealth interoperability at the national and European levels.  
  - Increasing mobility of patients within internal market of health services. | - 1. Transborder medical services available  
2. Accessibility of telemedical services  
   – number of institutions offering the services, | - questionaire research of patients  
   - statistics of the National Health Found and the Central Statistical Office | Logistic and human resources commitment on the part of the beneficiary maintained.  
Professional staff involved in the project. |

| Results | Objectively verifiable indicators | Sources of verification | Assumptions |
### Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare

<table>
<thead>
<tr>
<th>Task</th>
<th>Descriptions</th>
<th>Reports, Certificates</th>
<th>Logistic and Human Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis of the importance of the WHO / CEN/ISS standards that are of crucial value on the e-Health legislation across</td>
<td>- text of the document</td>
<td>- text of the adapted version of standards</td>
<td>- commitment on the part of the beneficiary maintained. Professional staff involved in the project.</td>
</tr>
<tr>
<td>a draft of regulations regarding the control of standard observation will be prepared</td>
<td>- text of the document</td>
<td>- text of the handbook available</td>
<td></td>
</tr>
<tr>
<td>a draft of regulations regarding the design of data communications systems in healthcare</td>
<td>- the adapted version of standards indicated by WHO and CEN/ISS, crucial for development of e-Health available</td>
<td>- the approval tests applicable</td>
<td></td>
</tr>
<tr>
<td>all standards indicated by WHO and CEN/ISS, crucial for the implementation of the technical platform for the open source and interoperable eHealth solutions, adapted</td>
<td>- the handbook available</td>
<td>- website fully operational and available</td>
<td></td>
</tr>
<tr>
<td>handbooks with guidelines for end users regarding standards application prepared, approval tests to investigate the compliance of systems with European standards prepared,</td>
<td>- text of the adapted version of standards</td>
<td>- approval tests</td>
<td></td>
</tr>
<tr>
<td>a website promoting standardisation of data communications systems in healthcare</td>
<td>- text of the handbook available</td>
<td>- access to the website</td>
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</tr>
<tr>
<td>Approx. 16 trainers trained in standardization in data communications systems in healthcare</td>
<td>- Approx. 16 trainers prepared to disseminate their knowledge in central healthcare institutions (Ministry of Health ,The National Health Fund, National Centre for Health Information Systems)</td>
<td>- the guidelines prepared and available</td>
<td>reports, certificates from the trainings</td>
</tr>
<tr>
<td>good practice guidelines for</td>
<td>- providers and users of medical information systems in the field of standardization of the healthcare-related data collecting and managing trained</td>
<td>- text of the guidelines</td>
<td>- text of the guidelines- reports, certificates from the trainings</td>
</tr>
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</table>
Implementation and Control of Application of European Standards for Data Communications Systems in Healthcare

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Sources of verification</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>- outlining regulations regarding the development of standard-abiding data communications systems in healthcare which are in compliance with the standards</td>
<td>Twinning light contract signed (4 STEs), trainings, seminars, workshopsTA contract signed</td>
<td>Co-financing from the Polish budget ensured. The timely realisation of the TF 2004 project. Professional staff involved in the project.</td>
<td></td>
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<tr>
<td>- outlining legal procedures providing framework for controlling application of standards in data communications systems in healthcare</td>
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<td>- preparing and adapting selected more important standards indicated by CEN/ISS regarding data communications technology in healthcare for the purpose of implementation in the legislation and training processes</td>
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<td>- preparing handbooks with guidelines for end users regarding standards application</td>
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<td>- preparing approval tests to investigate the compliance of systems interface as for European standards compliance</td>
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<tr>
<td>- building a website promoting standardisation of data communications</td>
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</tbody>
</table>
systems in healthcare. The site will provide continually updated information and guidelines for users and designers of data communications systems in healthcare
- conducting advanced trainings for trainers in standardisation in data communications systems in healthcare
- seminars and trainings for healthcare managers, the staff of medical care units that is responsible for data flow and management, health practitioners

| Preconditions | - declaration of co-financing |
### Annex 2-3: Implementation, contracting and disbursement schedules

<table>
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<tr>
<th>Date of drafting</th>
<th>20.10.2005</th>
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<td>Implementation and control of application of European standards for data communications systems in healthcare</td>
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<table>
<thead>
<tr>
<th>Planning period</th>
<th>01.2006 – 12.2007</th>
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<tbody>
<tr>
<td>Budget allocation, cost estimate in MEUR</td>
<td>0.481 (TF)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Contract 1</strong></td>
<td></td>
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</tr>
<tr>
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<td>D</td>
<td>C</td>
<td>I</td>
<td>I</td>
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<td>Contracting</td>
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<tr>
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<td><strong>Contract 2</strong></td>
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<tr>
<td>Implementation</td>
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<td>D</td>
<td>D</td>
<td>C/I</td>
<td>I</td>
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<tr>
<td>Disbursement</td>
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<td>0.330</td>
<td>0.330</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Legend:**

- D – design of contract and tendering
- C – signature of contract
- I – contract implementation and payments