Terms of Reference for Development and Deployment of the Cancer Register Information System of Serbia

Ver 1.2

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1 INTRODUCTION

Cancer is a significant public health problem in the Republic of Serbia. An average of 36,000 new cases of cancer are diagnosed annually, with over 20,000 people recorded dying from cancer. Serbia is in a group of countries with a medium risk of disease (ranked 12th out of 40 countries in Europe) and a high risk of dying from it (in Europe second only to Hungary). Cancer of lungs and bronchus are the leading localization in both disease and death among men, and third most common cause of disease and the second cause of death among women diagnosed with cancer. Cancer of colon and rectum are the second most frequent cancer localization in disease and dying in men, and second in the incidence of disease and third in dying from malignant tumors in women. The third most common malignancy in men is localized to the prostate gland. Cervical cancer is the fourth most common malignant tumor in the disease and the sixth most common in women to die.

Reducing the burden of cancer in Serbia is a major endeavor involving doctors, epidemiologists, researchers, legislators and others. They all rely on cancer data in their work. Doctors need cancer data to find out more about the causes of cancer and to detect cancer earlier, at earliest stage as possible, increasing cure and survival chances. Treatment decisions are made based on accurate cancer data from sources such as pathologist and cytologist reports. At the end of treatment, doctors still need cancer information to monitor the patient's condition long enough to determine if treatment has succeeded and, if not, to determine why not. Monitoring over the life of the patient is another important aspect of the cancer registry, which provides accurate survival information.

Health policy makers use cancer registry data to make public health decisions that maximize the effectiveness of limited funds from cancer funds, such as implementing screening programs. A cancer registry is a valuable research tool for those interested in the etiology, diagnosis and treatment of cancer. Cancer data can indicate environmental risk factors or risk behaviors, so preventive measures can be taken to reduce the color of cancer cases and cancer deaths.

In short, the significance of the cancer registry lies in the fact that it collects accurate and complete cancer data that can be used for cancer control and epidemiological research, planning a public health program, and improving patient care. Considering the high burden of malignant tumors in Serbia, it is very important to have adequate information to help develop prevention and cancer control strategies, as well as planning appropriate oncology services and oncological care for patients. Only a well-organized cancer registry can enable such information to be obtained.

2 PROJECT OBJECTIVES

The overall project objective is to replace existing application software, CanReg 4, and provide support for improved business processes and practices employed by the Cancer Register for Republic of Serbia (population-based). The project should deliver smooth, predictable transition from usage of CanReg 4 with many local deployments to new information system with improved operational practices and business processes. The project shall, as minimum, provide:

1. Development of information system for the Cancer Register for Republic of Serbia;

2. Procurement, installation, configuration and operational deployment of software infrastructure for new information system (operating systems, databases, middleware software);
3. Migration and consolidation of existing databases;
4. Training for end users and administrators;
5. Provision of support and maintenance services;
6. Proposal for long term support for information system;

Achievement of each phase shall be subject of acceptance procedure using previously agreed metrics.

3 BUSINESS GOALS AND PURPOSE OF CR-IS

The Cancer Register Information System of Serbia (hereinafter: CR-IS) shall be utilized to improve existing practices in collecting and processing cancer related data, in creating standardized statistics and getting deeper insights in cancer trends, as well as dissemination and practices regarding availability of information. Business objectives that CR-IS shall support are:

1. Improve monitoring of cancer burden and its changing trends over time across the regions and in Serbia as whole;
2. Quicker assess magnitude of the cancer burden and its likely future evolution;
3. Better and tighter connection between data and information served to illustrate and apprise effects of health policy interventions aimed at reducing the overall cancer burden;
4. Establish reliable, easy to access and use, reference data base for cancer epidemiological research;
5. Provide data and information to further research on possible underlying causes of cancer as well as best practices on prevention, treatment and control;
6. Provide information and educational resources to general public to explain and educate on trends and variations observed in different populations;
7. Ensure international comparability of cancer burden according to standards set by the European Network of Cancer Registries (ENCR).

Central part of the project is development and deployment of information system for cancer register. The CR-IS shall, as a minimum, provide:

1. Support for processes and functions as prescribed and required by methodology for collecting, processing and reporting on cancer, which is based in legislation regulating health records in field of health;
2. Analytical tools that will allow the Cancer Register's staff, i.e. institutes for public health, creation of ad-hoc reports and analytical work, including features such as data drill, national and international benchmarking, with historical, current and predicted trends;
3. Introduction of relevant reports for all users of the system, subject to user rights and roles, and relevant institutional level;
4. Automated exchange of data with software solutions employed in health organizations that are sources of cancer reports, according to common rules; and

5. Utilization of services of information system platform of the Institute of Public Health “Dr Milan Jovanović Batut”.

4 REQUIREMENTS FOR CR-IS

4.1 Functional requirements

Functional requirements represent the basis of the information systems, and define what the information system is supposed to do, i.e. its functions, features, services and operations. Functional requirements include:

1. Description of the processing that the system must perform,
2. Details of inputs into the system,
3. Details of the expected outputs of the system,
4. Details about the data that must be stored in the system.

No	Requirement description	Reference to sections
1	Solution shall provide a register of all persons that are reported suffering from cancer as described in business processes.	4.3; Annex 1
2	Solution must store the required data and information on persons that are reported as persons with malignant tumor. For each person master data set must contain all variables (fields) from the registration form and data from other forms relevant for update information. The entire history of changes in health status (incl. initial record creation) must be kept for each person.	Annex 2 Annex 5
3	Solution shall support business processes used in registration and management of cancer cases in population based Cancer Register of Serbia. These are: (1) Initial registration of person with a cancer; (2) Update of records about patient and/or status of cancer(s); (3) Closing patient record(s). The processes shall be supported as a workflow(s). Processes are described in 4.3 Business processes to be computerized	4.3
4	Solution must support using multiple data sources for tracking patient and cancer(s) statuses.	4.3,
5	Solution must support automatic and manual joining of patient records i.e. to have capability to search for and recognize duplicate records.	4.3
6	Solution must provide tools for error detection and correction in cancer reports using methodology for data quality of ENCR.	4.3;

No	Requirement description	Reference to sections
7	Solution shall provide traceability and mapping of cancer cases through application of different versions of International Classification of Diseases for Oncology (ICD-O-3).	Annex 9
8	Solution must offer advanced search capabilities for finding records by any of attributes of patient or cancer, within selected time period.	4.6.1
9	Solution must offer a reporting tool that will allow reporting on individual and as aggregate for any given time period using variables that are used for standard data collection.	4.7; Annex 2;
10	Solution shall offer publicly visible reporting facility, which will allow public (unauthorized user) to explore cancer incidence and mortality in interactive mode. Interaction includes selection and/or isolation of data elements, and drill-down on report elements. Solution shall show data in (1) tabular and (2) graph for this type of data, while it shall be possible to get distribution(s) of observed phenomena on a (3) map, according to selection. Data explorer shall employ filters for data selection: (a) Municipality/county (b) Gender (male, female) (c) Cancer (all cancer types) (d) Age (e) Year (f) Indicator (Incidence, Mortality, etc.) Data explorer shall allow to explore data, reporting separately on: (1) national estimates of cancer incidence and mortality for the most recent year, (2) incidence and mortality indicators over time (historical data until the most recent available year), and (3) national survival estimates. All the possible analyses shall be displayed in through maps, charts, and tables, according to the indicator (incidence, mortality, survival) and the scenario selected (analyses specific for cancer site, analyses by cancer, analysis by municipality/county).	4.6; 4.6.1.17; 4.6.4;
11	Solution must support automatic data exchange with information systems of health institutions in charge for treatment of patients with cancer, by providing web service interface and using standardized schema.	4.6;

No	Requirement description	Reference to sections
12	Solution shall support data exchange with information system of institution in charge for reporting on death cases, by providing web service interface and using standardized schema.	Annex 5
13	Solution shall utilize services deployed by the Institute of Public Health of Serbia interface: Public Health e-service(s). Interfaces will be two way with the interface for reporting data, status or errors back to the service requestor.	Annex 8
14	Solution must provide configurable business rules for logical data validation for all cancer types.	Annex 9
15	The interfaces must be able to perform data validation (presence and syntax checking of all fields).	4.6.
16	Logical data validation will be possible in both web application and web service.	
17	Solution should take every opportunity in web app to facilitate data entry to prevent the user from accidental errors and “automatic” entry of values, such are cancer diagnoses. Solution shall deploy two-way mechanism that will lead user in entry of key aspects of cancer definition.	4.6.1.
18	Solution must support tracking status of patient cases as reported into system by health organizations (submitted, additional registration details / documents / information requested, review, accepted into the register).	4.6.1.
19	Solution shall support creation of ad hoc queries and generation of custom reports (self-service reporting) to enable users to analyze the data, without relying on IT/business analyst to create a report.	4.6.1.8
20	Solution shall support export of data sets created through analysis (predefined and self-service) to standard data formats used for office automation and collaboration. Solution shall provide possibility to save custom queries and reports as templates for future use (including document formats, formulas, data used for retrieval and analysis).	
21	Solution shall provide basic predictive modeling and data analysis, classification of categorical variables and estimate continuous variables using mathematical and statistical techniques.	4.7.2
22	Solution should be able to export data/ data sets in various file formats (JSON, delimited, excel sheets etc.)	4.8.6.2

No	Requirement description	Reference to sections
23	Solution shall support efficient management of user accounts, their rights and privileges. User management will rely on Batut's directory of persons employed in health institutions in Serbia.	4.8.1.4; Annex 8
24	End user must have the ability to change the password whenever they want, and the system has to "compel" the end-user to change the password in accordance with the security policy.	4.8.1.4;
25	By applying authentication and authorization mechanism CR-IS system should ensure that system users are the ones who they represent to be, as well as to provide them with access to certain parts of the system on the basis of their rights and privileges.	4.8.1.4; Annex 8
26	Solution shall be implemented in a multilayered architecture and must provide access to end users through Web browsers (as clients).	4.5
27	The Software solution shall feature: 1) simplicity and functionality of application design, 2) user-friendliness, 3) contextual help / instructions provided for each window and each entry cell, 4) upgradeability in terms of adding new modules, interfaces, OLAP structures and analysis based on them, 5) flexibility, 6) configurability of all parameters that define the user interface and allow proper execution of the intended functions, 7) transparency, 8) provided interoperability through all standard interface types (export / import of data in JSON and / or structured TXT format, WEB application services), 9) quality documentation and transparency of the design and code of the application, 10) ability to reconstruct the state of the system at any past date.	4.6
28	The system must comply with the legal requirements on data privacy, documentation in health care sector, use of electronic documents, electronic identification and trust services.	Annex 1, 1.2;
29	Application and database collation must support the use of Serbian in both official letters: Cyrillic and Latin.	4.2.2
30	Software solution shall provide tools that will make possible: 1) development of custom queries,	4.6.1.

No	Requirement description	Reference to sections
	2) development of custom reports, 3) database management and optimization.	
31	The system will allow automatic recording of the data entered often enough to avoid losing a significant amount of data entered in case of violent or other unnatural termination of the web session.	4.6.1

4.2 Non-functional requirements

Non-functional requirements of CR-IS describe expectations, constraints, objectives and requests to service that the software solution shall provide. Non-functional requirements support, as well as functional requirements, integrity and usability of the system as a whole. They specify different operational parameters that define the solution and specify the criteria used to assess the functioning of the system. Non-functional requirements define the features that the system will provide to the user.

The most important non-functional requirements which CR-IS needs to fulfill are:

No	Requirement description	Reference to sections
1	Scalability. CR-IS must be scalable and be able to "handle" the increase of data load and as well concurrent users in peak periods. System must provide mechanism for automatic scaling up and down of resources needed to meet consumption.	5.1; 5.3
2	Competitiveness. CR-IS must provide competitive access to all end users of the system, while the performance of the system should not be undermined.	4.8.1.1
3	Reliability and stability. CR-IS must at all times be available for use and be "prepared" for unforeseen circumstances such as the loss of electricity in order to preserve the consistency of all data used and stored.	5.3; 5.4
4	Backup. It is necessary to ensure backup of the data contained in the database, and backup of log tables or log files. It should be possible, at any time, to recover deleted data or their earlier versions. In addition, stealing backup must not lead to compromising of the data stored in it. Contractor is expected to implement backup procedures in such a way that it automatically performs a full backup in time interval that will be controlled by an administrator. The Contractor shall provide tool for a daily check of the validity of the backup, in such a way as to perform restore of databases on the copy of database system and perform basic parameter checks.	4.6; 6.15

No	Requirement description	Reference to sections
5	History. The Contractor is expected to ensure that the history logs of all relevant activities (login to the system, data altering, creating data, deleting data ...) is kept for time period that will be possible to specify by a system administrator. This requirement shall be implemented in synchronization with public health (e)service provided by the Institute of Public Health of Serbia.	4.6; Annex 8
6	Security. CR-IS shall fulfill criteria of confidentiality, integrity, authenticity and availability of data. In addition, it is important that the property of non-repudiation be fulfilled. The CR-IS shall provide multi-layered security, while it consists of the following three levels: 1. Protection "end-to-end" at the application level, which is based on the application of digital signature technology based on asymmetric cryptographic algorithms and confidentiality of the data using symmetric encryption algorithms. 2. Protection on the transport level represents protection of confidentiality of data using symmetric encryption algorithms and authentication of nodes of the communication segment of the network. This level is aimed to protect the network from internal and external attacks by applying cryptographic tunnels (protected sessions) between nodes of the communication network segment on the basis of the symmetric cryptographic system and application of procedures of "strong" authentication between network nodes, thus providing the authentication check of parties in communication. Additional use of an asymmetric cryptographic system should be considered to protect the integrity of data transmitted through the network and non-repudiation of emission of the given data. 3. Protection at the network IP level to provide a cryptographic and logical protection at the level of IP packets, which are exchanged between network nodes. To protect from external attacks, CR-IS should use: protective mechanisms which are provided by a standard communication equipment, protection through application of "firewalls" and the IP filtering, protective mechanisms on the network level which are provided by the operating system itself, but also "strong" physical protective measures for access to network equipment and servers.	4.8.2
7	The data exchange module must be able to support secure communication through standard Internet protocols.	4.8.2

No	Requirement description	Reference to sections
8	Data exchange with external information systems will be implemented on “need-to-know” basis to enable "concealing" of the information about the persons in cancer register. External information system shall have a minimal piece of information to enable start of data exchange with cancer register.	4.8.2
9	Availability. The system shall to be available 24 hours a day, 7 days a week, except during periods of scheduled maintenance, upgrading and backup.	
10	Processing of data received through data inputs or interfaces must not affect the rest of the system except when the data directly processed.	5.1
11	Logging activities system-wide. All user activities must be recorded in appropriate logs maintained in such a format that their use is simple, transparent and effective in all cases of their use: 1) providing customer support, 2) forensics of disputed situations, 3) monitoring user activities, 4) proving possible user responsibility.	Annex 8;
12	The coding method should be maximally flexible with the use of parameters / variables instead of fixed sizes to facilitate tuning and maintenance when changes in user requirements occur.	
13	No deleting records is allowed in databases, regardless of their origin, including user errors. This principle may only be waived in the pre-entry phase, i.e. before sending complete sets or sub-sets of data to the server. However, from the moment of the first confirmation of the entered / imported data onwards, the status of each record in the tables (including related records in other tables) shall be remembered and clearly marked in case of need for reconstruction.	4.6; 6.15;

4.2.1 User Interface

No.	Requirement	Reference to sections
1	Usability. CR-IS GUI will be as much as possible adjusted to users and their roles (workplace). Features and ways of using of the system should be adapted to specific roles, limiting interactions with the system on elements and actions that are necessary to perform tasks normally granted to a user (based on actual work).	4.6

	It is necessary to find the optimal measure between facilitating the work of users and simplicity on the one hand, and protection from errors and ensuring clear accountability for the actions performed on the other.	
2	CR-IS GUI should look the same and the functionality should be implemented and supported in the same manner. At the same, it is necessary to respect the general rules for creating user interfaces, such as: – Consistency - certain parts of the interface should be unchangeable within the whole application (icons, terminology, color, ways to warn the user, etc.). – Simplicity - refers to decomposition of complex or long sequences into simpler and separate steps. – Navigation - implies the existence of a navigation bar that enables users to, at any time of using the application, know exactly which option is currently used. – assistance within the application - it is necessary to implement reminders, warnings and explanations for all essential features of the applications – Logicality - implies the use of appropriate, intuitive, graphical symbols (icons) for each individual application's functionality. – Feedback - implies getting the right feedback about successfully / unsuccessfully performed operation, etc... – System messages - implies getting appropriate textual - graphic messages about possible problems occurring during working with the application. It is necessary to avoid numerical labeling of errors, as well as the default error messages and "stack trace" prints. Different types of system messages should have a different graphical marking and eventually a text message or a frame drawn with a different (appropriate) color. – Modality - implies enabling users to work in the appropriate mode-regime, which is different from other modes, according to the activities performed by the user. Diameters of modes are: data entry, update of existing data, data review, etc.	4.6
3	The system should allow for customization of the user interface or non-display of forms / templates / reports for entering / viewing data that are not needed, i.e. they are not used in a particular type of institution.	4.6.1; 4.6.2
4	The end-user interface (menus, screens, error messages, on-screen reports and printed reports, etc.) should be available in both Cyrillic and Latin variants of Serbian language with the option of selecting a letter variant.	4.2.2
5	Where previously entered information limits the possibilities for further processing, these options will not be available in the interface and appropriate	

	warnings and instructions will be given to a user on how to return to the previous state if desired.	
6	The values that caused the collision with the implemented application controls / input rules will automatically turn the system color used for warring (e.g. red color).	4.6.1
7	The user environment should allow for optimal organization of work according to user roles, which will allow the user to perform all necessary actions within the same module without having to close any window or open a new instance of the application / tab in web browser wherever it is possible. The system will allow multiple windows to be opened with the same or different user context.	4.6.1
8	In the event that the user needs to take a step back in a sequence of steps, it should always be possible to reach the initial window for a specific action while preserving the context that existed at the moment of moving back and forth. Forward and backward navigation should be via dedicated commands, not through commands from web browser.	4.6.1
9	The system must provide contextual assistance, namely: 1) at the function level, 2) at the form / input level, 3) at the level of the entry form / window item.	4.6
10	Syntactic and semantic validation of the data and the cross-validation of the data must be performed when entering the data.	4.6.1
11	Any error encountered will return contextual feedback to the user's screen in the form of a message.	4.6.1
12	It must be possible to address errors following displaying an error or warning message and not by abnormally interrupting / terminating the program. Error messages must provide instructions to the user on what to do next after facing the error.	4.6
13	The system should allow for customization of the user interface by type / group of institution and / or individually at the level of a particular institution (primarily related to the visibility of certain reporting categories.	4.6

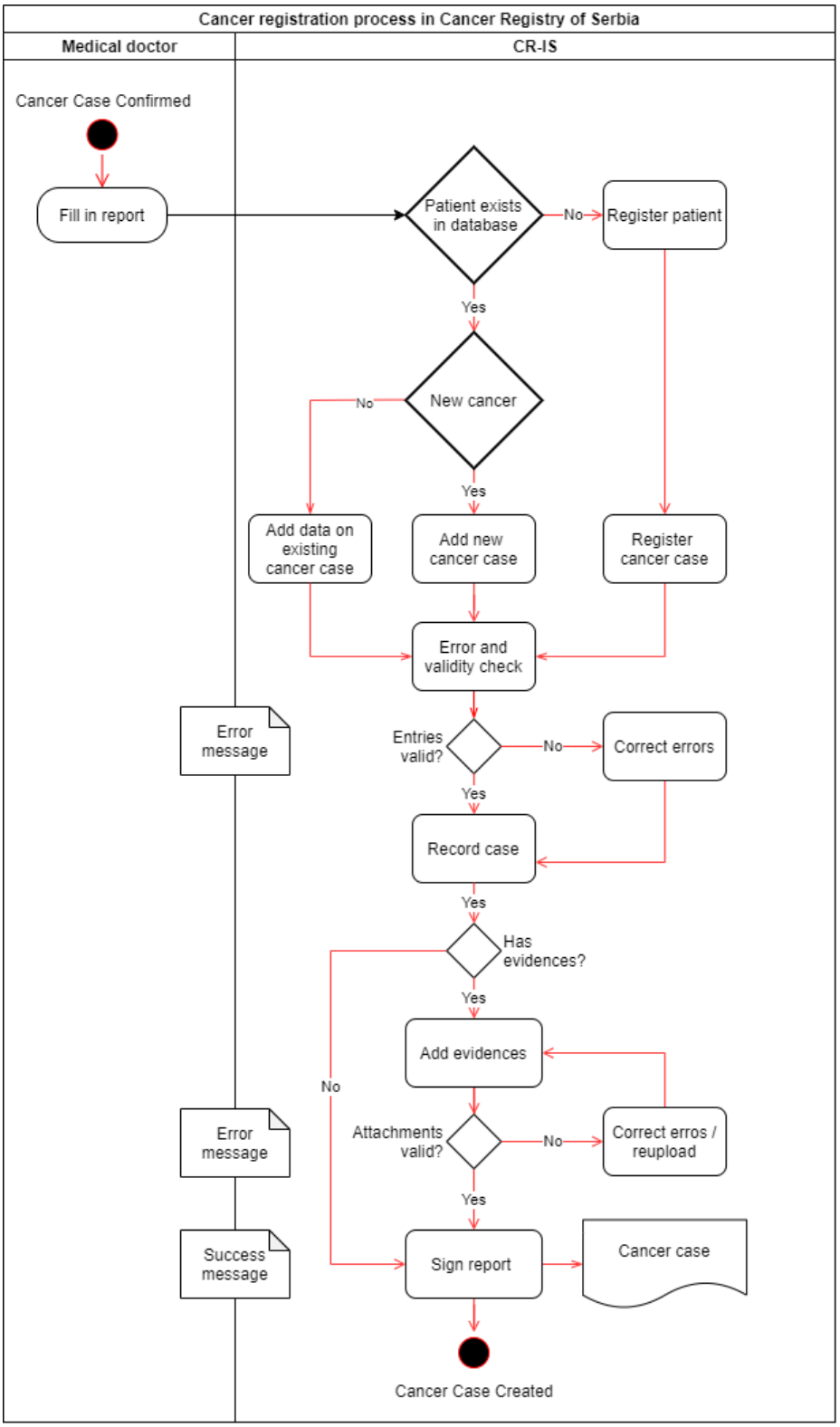
4.2.2 Localization

Solution must support the UTF-8 character set and support localization. Data sorting on a display should be enabled according to Cyrillic, but also to the Latin alphabet, depending on the selected font in the current session. Support for the proper presentation, computing and date sending is required.

4.3 Business processes to be computerized

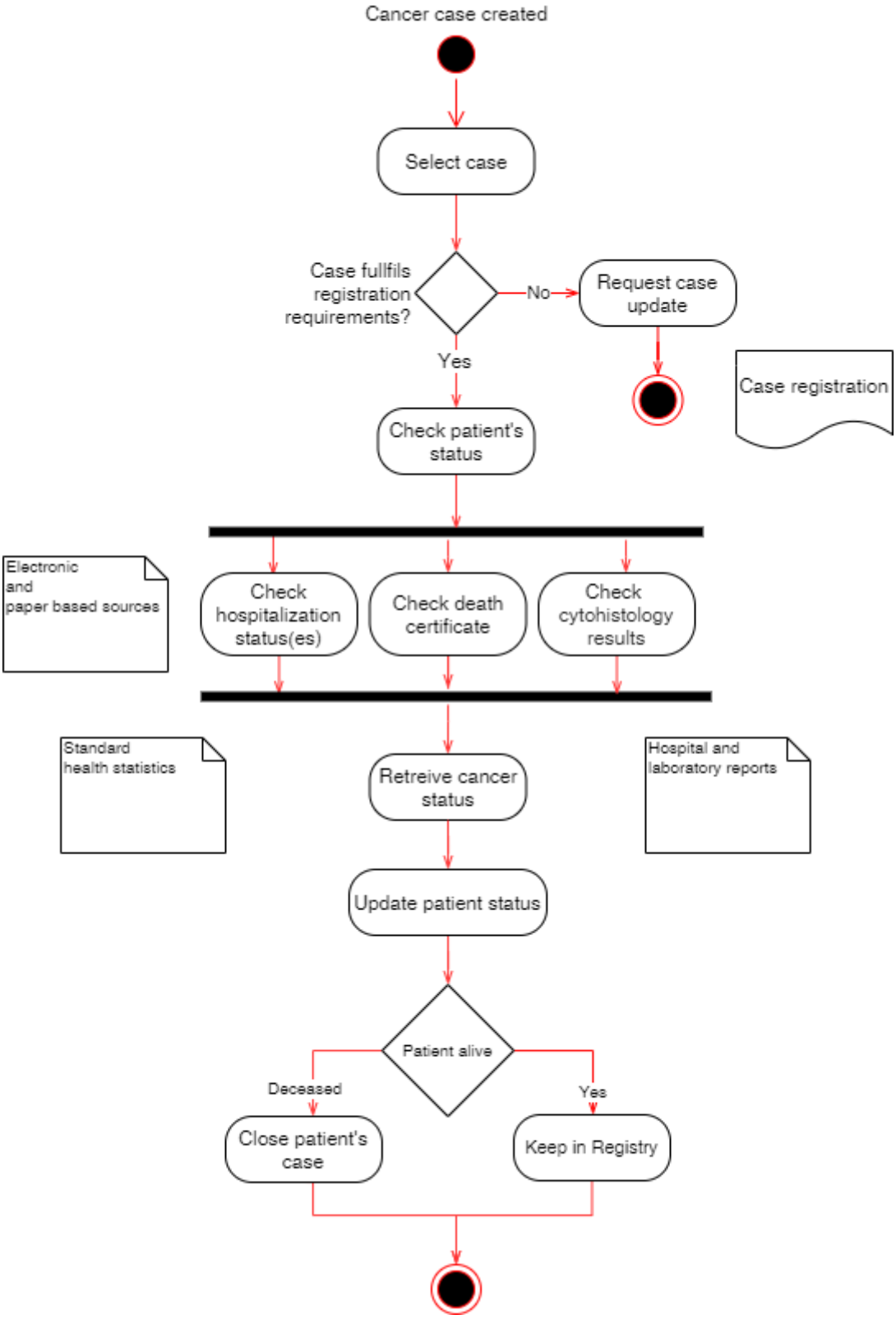
4.3.1.1 Register person with malignant tumor

Medical doctor performs registration of person with malignant tumor after a cancer case is confirmed by previously conducted diagnostics and examination(s) procedures. Medical doctor shall effectively sign off the registration as legal medical document.



4.3.1.2 Monitoring status of cancer cases

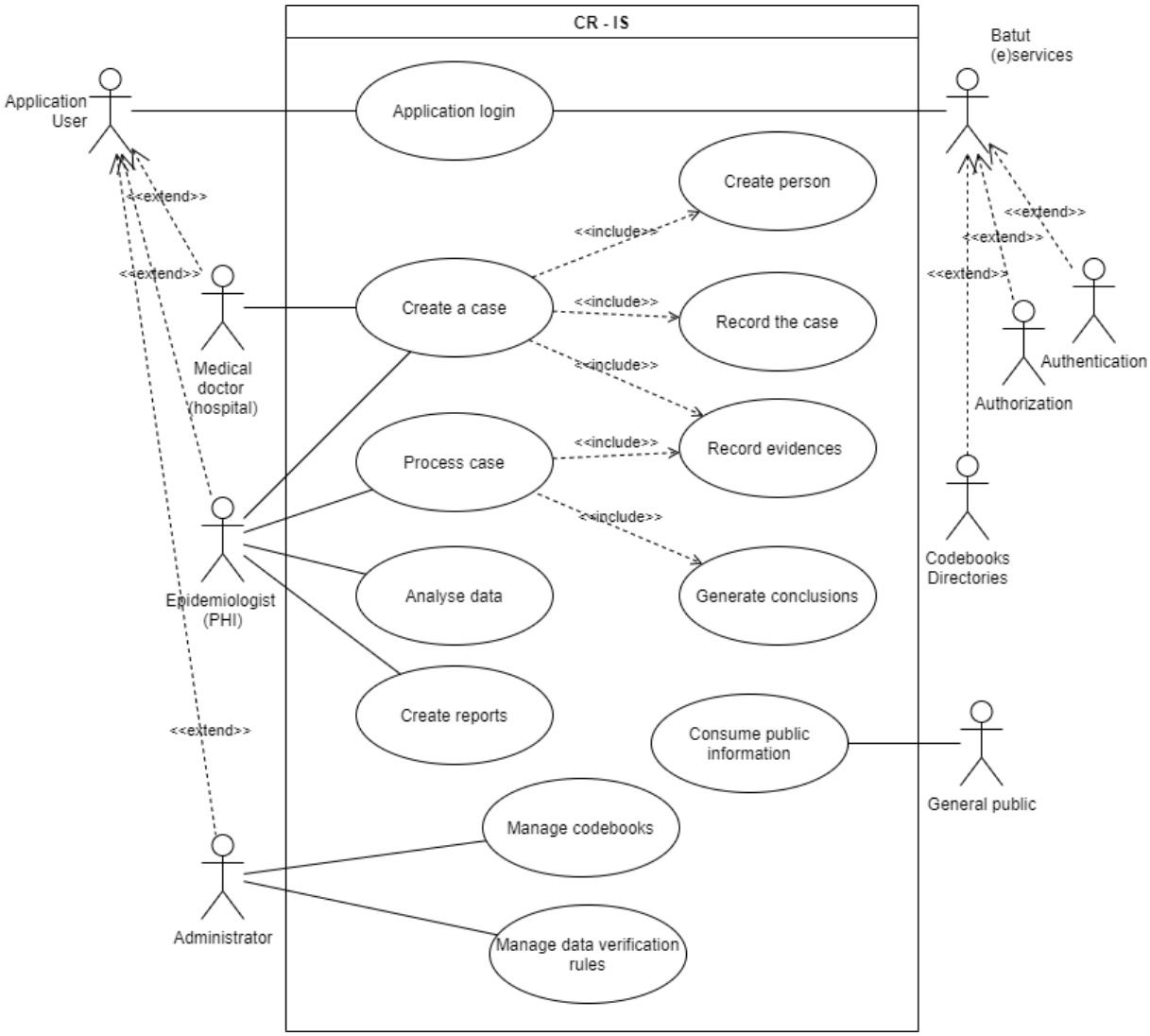
Cancer Registry epidemiologists monitor status of patient and cancer case(s) by comparing Registers's cancer cases data with data available in individual patient reports databases and reconciliate health ourcomes.



4.4 Use Cases of CR-IS

Use cases of the CR-IS on which the following participants are identified:

- medical doctor at oncology unit of a hospital,
- a user in the county institute for public health,
- a user in the Institute of Public Health of Serbia,
- the administrator of the CR-IS application,
- Batut services: user recognition and authorization and health statistics,



The prerequisite for all use cases except for general public use is that the application user is previously authenticated and authorized by CR-IS.

Actor	Actions
Medical Doctor (hospital)	a. Enters data for registration of case of a person with malignant tumor a.1 Creates personal record if person is not previously recorded in the Registry) a.2 Records details about cancer (describes cancer characteristics) a.3 Add additional documents that support registration of cancer case and its outcomes later for each registered case b. Signs the registration report for a case c. Submits the registration report for a case d. Corrects the data (registration form) returned for revision
Epidemiologist (at county institute of public health)	a. Reviews a registration form b. Perform checks and orders return of a case for revision if necessary c. Approves adding case of a person with malignant tumor into the Register d. Analyze data e. Create reports
Epidemiologist (at Institute of public health of Serbia)	a. Reviews a registration forms b. Perform checks and orders return of a case for revision if necessary c. Approves adding case of a person with malignant tumor into the Register d. Analyze data e. Create reports a. Uses data to write complex reports (data export) f. Approves data set & reports for external use
CR-IS System Administrator	a. Manage code books b. Manage data verification rules
Batut Information Resources (RBI)	a. Authentication b. Authorization c. Validates submitted codebooks data from healthcare institutions d. Raw data web site e. For logging actions from forms

4.5 System architecture

Proposed architecture is indicative and can be adapted during the detailed system analysis phase. The CR-IS should be implemented in a multi-level architecture, with the following key elements:

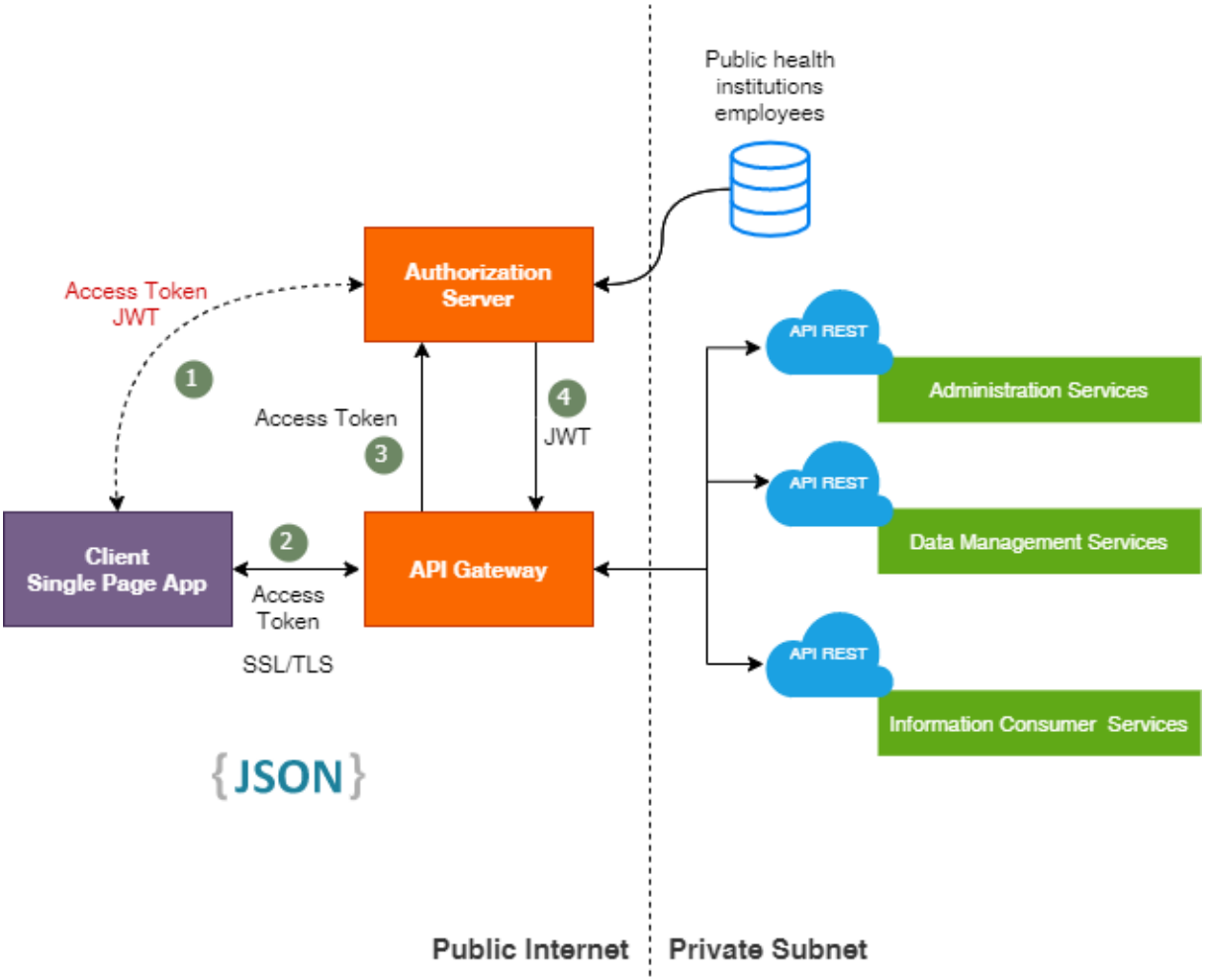
The single page web application (client) which users access via an HTTPS protocol, with respect to the appropriate security mechanisms. The web application should be implemented using MVC (Model-View-Controller) pattern. As alternative, other modern patterns (model-view-whatever) can be taken into consideration, if Contractor can demonstrate advantages of proposed pattern over the MVC. It is important to announce that the proposed architecture and structure of software modules are indicative as well and can be adapted during the detailed system analysis phase.

The application will use authentication and authorization service of Institute of Public Health of Serbia before communication with API gateway. Following APIs shall be implemented:

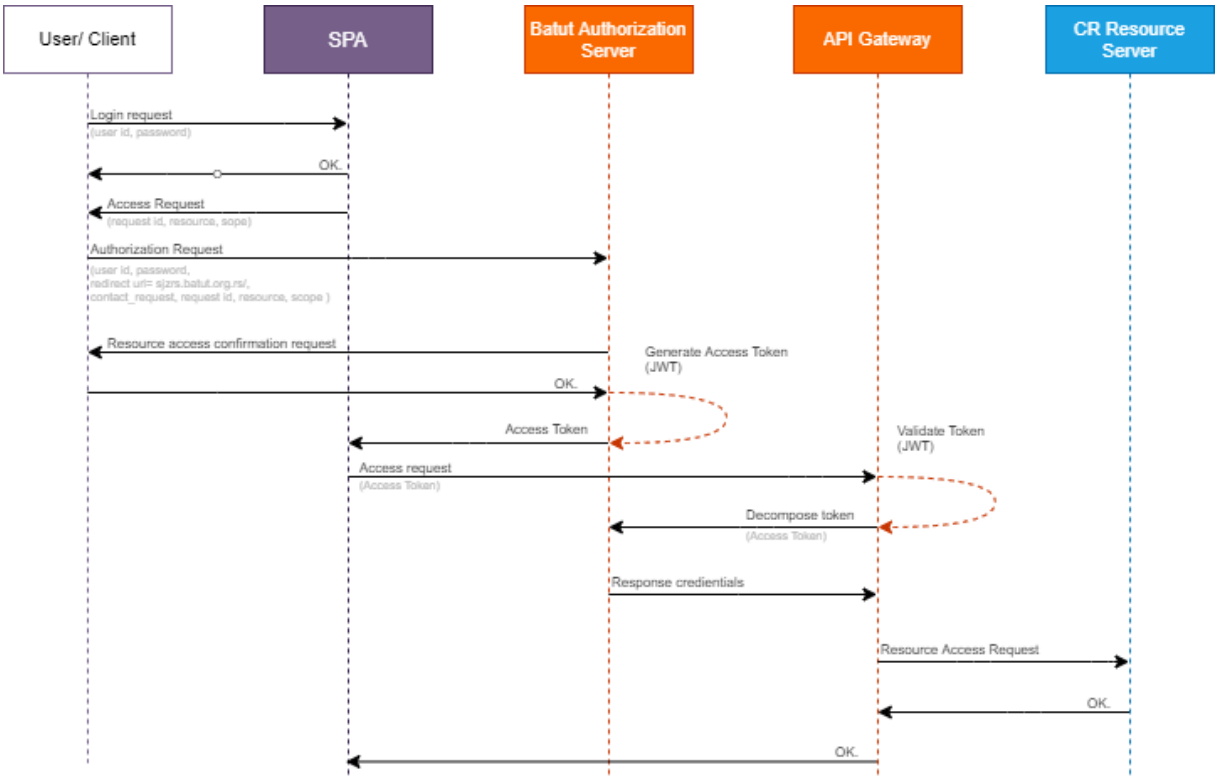
Administration Services – for managing admin related tasks;

Data Management Services – for data processing tasks (data entry, import, exchange);

Information Consumer Services – for consummation of information on cancer (presentation of calculated values from processed reports)



Following communication sequence show communication within CR-IS and utilization of Public Health (e)Services of Public Health Institute of Serbia.



4.6 Software modules (functional description)

The proposed basic modules of the Cancer Registry information system are:

1. Single Page App Client
2. Administration Services API
3. Data Management Services API
4. Information Consumer Services API

Proposed software modules are indicative and should be adopted in accordance with findings during system design phase.

4.6.1 Single Page App Client

4.6.1.1 Login page (common)

The login page allows registered users to login to the application and access features allowed by access rights. Standard combination of username and password credentials shall be provided. If login is unsuccessful, a user will get an error message. If the user has forgotten their password a "Forgot Password?" function will lead them in procedure to recover password. Login page should communicate with Batut Authentication Service in order to pull valid user token.

4.6.1.2 Control panel (Administrator)

Control panel displays links to services and actions that a user with Administrator privileges can execute. Control panel displays stats on data collection, system load, system messages, status of tasks in workflow, status of administrative tasks, tracks and reports website traffic.

4.6.1.3 Code book list (Administrator)

Shows list of codebooks used in system for purpose of data collection, control, functions calculation and indicator value display. The list should contain codebook name, corresponding identification, dates of creation, version, status with possibility to search and filter for specific value (ex. key word, category).

4.6.1.4 Code book management (Administrator)

Codebook management allows creating, viewing or modifying code books used in system. It provides historical tracking of changes in codebooks by versioning. Display list of forms, reports, and controls where a code book is used.

Codebook Management shall allow CR-IS to connect to codebook repositories serviced by Public Health (e)Service of Institute of Public Health of Serbia, over time period and make them comparable.

4.6.1.5 Report list (Administrator)

Shows list of reports created in system, based on registration of cancer cases. The list should contain name of reports, or corresponding identification, dates of creation, status of report (in use, draft, phased out, etc.) with possibility to search and filter for specific value (ex. key word, category).

4.6.1.6 Report Builder (Administrator)

Report Builder enables user to create, view, modify and phase out a paginated reports. Report Builder shall provide graphical interface with drag-and-drop functionality to form a report. Report Builder will support creation of reports using calculated values, with possibility to define custom level of details reported, define measurement units, create summaries and simple tables, view report based on report parameter value.

System shall be delivered with set of predefined reports (see 4.7 Reports).

4.6.1.7 Control panel (Data Management)

Control panel displays links to services and actions that a user can execute. Control panel displays stats on cancer cases, system messages, status of cancer cases in a workflow, status of administrative tasks, tracks and reports. Header section contains information for user to inform on role, institution, user itself, relevant system statuses.

4.6.1.8 Search cancer/person case (Data Management)

Search and select patients/cancer or subset, depending of search criteria (based on variables). Search shall allow a user to (1) sort, and (2) filter results, using expressions.

4.6.1.9 Form CRUD (Data management)

Form allows user to enter cancer cases and related data, including cancer case evidences. Form will provide (1) registrations of persons/cancer case, (2) Status change(s) of registration/cancer, (3) Closure of registration of a person/cancer, (4) Join and unjoin of cancer cases / persons. Form shall implement all data checks, error checks, and lookup (codebooks). In case of error, an error message shows.

Form implements business process for data collection, monitoring and update of cancer cases (see section 4.3).

4.6.1.10 Compare and join cancer/person case (Data Management)

Compare cancer/person case enables selection of two or more cancer cases or patients in order to compare similarities / differences, including changes over time. If a user finds that cancer cases are a duplicate or that a patient is a duplicate, it will allow to perfom join of cases / patients in controlled manner (user chooses which data will be discarded).

4.6.1.11 Data Analytics (Data Management)

Provides standard statistical analysis of data using patient-cancer variables for conducting (1) descriptive statistics and (2) inferential statistics. Performed analysis shall be possible to export to a report. Performed calculations and steps shall be possible to save as a template.

4.6.1.12 Report Viewer (common)

Displays defined reports as a document that can be downloaded, printed or copied. User can choose format in which report shall be saved.

Reports' export to formats are defined in section 4.8.3.2 Report formats, and presentation style.

4.6.1.13 Control panel (Information Consumer)

Displays links to services and actions that a user can execute.

4.6.1.14 Report List (Information Consumer)

Shows list of reports that are approved for usage. The list should contain name, group, with possibility to search and filter for specific value (ex. key word, category).

4.6.1.15 Report Viewer (Information Consumer)

Shows data served by Information Consumer Services API in various views. Viewer will allow exploration of calculated data on cancer through display, according to selected report. Viewer shall show data in (1) tabular and (2) graph forms, as well as on (3) map to inform on distribution and dispersion of observed phenomenon, according to selection. The Viewer shall offer search and filtering to narrow selection and to explore it. It will be possible to explore data using "drill down" principle and to compare results on an indicator by selection of reported entities (Serbia, county, facility, etc.) at different level of details. The exploration and comparison shall be possible against time dimension, in cases where such data exists.

4.6.1.16 Cancer Dataset export (common)

Cancer Dataset Export allows a user to export dataset to local storage. User shall have possibility to choose (standardized) format for export. (see 4.8.3.2 Report formats, and presentation style)

4.6.2 Administration Services API

4.6.2.1 Control panel

Serves links to services and actions that a user with Administrator privileges can execute. Serves stats on data collection, system load, system messages, status of tasks in workflow, status of administrative tasks, tracks and reports website traffic.

4.6.2.2 Code book list

Serves list of code books.

4.6.2.3 Code book management

Creates new and manages existing code books.

4.6.2.4 Report list

Serves list of reports.

4.6.2.5 Report builder

Creates new or modifies existing reports.

Serves and loads report definition to Report Builder. Saves the definition using report elements defined in Report Builder. Serves elements to define types of reports (tabular, graphical or free-form reports).

4.6.2.6 Report Viewer

Serves reports content and defines how report is displayed using user role.

Defines options for export to document formats.

Report export to formats are defined in section 4.8.3.2 Report formats, and presentation style.

4.6.3 Data Management Services API

4.6.3.1 Control panel (Data Management)

Serves links to services and actions that a user with Data Management privileges can execute. Serves stats on cancer cases, system messages, and status of tasks in a workflow, status of administrative tasks. Serves alarm on conditions that are out of expected data collection practice (such warnings shall change to fit user role).

4.6.3.2 Search cancer/person case (Data Management)

Serves a search form.

4.6.3.3 Form CRUD (Data management)

Serves a form for data entry / edit. Provides fields for meta notation of data or dataset (ex. comment). Shows data from previous form.

4.6.3.4 Compare and join cancer / person case

Serves cancer case / patients data sets to be compared and/or joined in SPA client.

4.6.3.5 Data analytics import (Data management)

Serves formulas to be applied on a data set and stores results for further usage.

4.6.4 Information Consumer Services API

4.6.4.1 Control panel (Information Consumer)

Serves links to services and actions that a user can execute.

4.6.4.2 Report List (Information Consumer)

Serves list of prepared reports, with possibility to search and filter for specific value (ex. key word, category)

4.6.4.3 Indicator Viewer (Indicator Consumer)

Serves data of selected indicator.

4.7 Reports

This section describes the reports that shall be implemented as predefined reports.

4.7.1 Individual reports

R.I.	Report name	Input parameters to create report	Reported result	Report form
1	(Number of) cancer cases updated	Start period, End period, Territorial coverage, health institution, data source (type)	Listing, count	Table

4.7.2 Statistical and analytical reports

R.S.	Report name	Input parameters to create report	Reported result	Report form
1	Number of new cancer cases by sex	Start period, End period, territorial coverage, cancer, sex (male, female, both)	Count, per cent	Table, Chart (type), Map (area)
2	Number of death cancer cases by sex	Start period, End period, territorial coverage, cancer, sex (male, female, both)	Count, per cent	Table, Chart (type), Map (area)
3	Standardized cancer incidence and mortality rates per 100.000 population	Start period, End period territorial coverage, cancer, sex (male, female, both)	Index	Table, Chart (type), Map (area)
4	Standardized cancer mortality rates per 100.000 population, males	Start period, End period territorial coverage, cancer, sex	Index	Table, Chart (type), Map (area)
5	Standardized cancer mortality rates per 100.000 population, females	Start period, End period territorial coverage, cancer, sex	Index	Table, Chart (type), Map (area)
6	The leading cancer sites by sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
7	Deaths for leading cancer sites by sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
8	Number of new cancer cases by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
9	Crude cancer incidence rates by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)

R.S.	Report name	Input parameters to create report	Reported result	Report form
10	Standardized cancer incidence rates by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
11	Number of death cancer cases by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
12	Crude cancer mortality rates by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
13	Standardized cancer mortality rates by sex and leading primary sites	Start period, End period territorial coverage, cancer, sex	Count, Per cent, Index	Table, Chart (type), Map (area)
14	Total number of new cancer cases and number and percentage of cases registered from death certificates only, of corpus uteri	Start period, End period territorial coverage, cancer, sex	Count, Per cent	Table, Chart (type), Map (area)
15	Number of new cancer cases by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent	Table, Chart (type), Map (area)
16	Crude and standardized cancer incidence rates per 100,000 population by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
17	Number of death cancer cases by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)
18	Crude and standardized cancer mortality rates per 100,000 population by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent, index	Table, Chart (type), Map (area)

R.S.	Report name	Input parameters to create report	Reported result	Report form
19	Total number of new cancer cases, number and percentage of histologically and cytological confirmed cancer cases, by primary site and sex, Central Serbia, 2015	Start period, End period territorial coverage, cancer, sex	Count, Per cent	Table, Chart (type), Map (area)
20	Number of new cancer cases and cancer incidence rates by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent	Table, Chart (type), Map (area)
21	Number of death cancer cases and cancer mortality rates by primary site, age and sex	Start period, End period territorial coverage, cancer, sex	Count, Per cent	Table, Chart (type), Map (area)

Definitions of report elements:

Adjustment. A summarizing procedure applied to a statistical measure in which the effects of differences in composition of the populations being compared have been minimized by statistical methods.

Age-specific incidence rate. An age-specific rate is the incidence or mortality rate for a specified age group, in which the numerator and denominator refer to the same age group; it is expressed as the number of new cancer cases or deaths per 100,000 population at risk. Five-year age categories are normally used (highest group 85+).

Age-standardized rate (ASR). The ASR is a weighted mean of the age-specific rates where the weights are taken from the population distribution of a standard population; the ASR is expressed per 100,000. Comparison of rates referring to different time periods or different geographical areas is only possible after considering the differences in the age structure of the underlying populations. The age-standardization allows the comparison of the rates that are arithmetically adjusted to have the same age structure of the standard population. The standard population used are the following old European Standard Population, new European Standard Population, and World Standard Population.

Crude rate. The crude rate is the ratio of the number of new cases or deaths in a specified population and time period to the size of the population at risk during the same time period. Incidence and mortality rate are usually presented as an annual rate per 100,000 persons at risk.

Cumulative risk. Cumulative incidence/mortality is the probability or risk of individuals getting/dying from the disease over a specified age-span. Cumulative risk is expressed as the

number of cases/deaths per 1000 person-years that are expected to occur in a given population between the specified age limits (e.g. between birth and the age 84 years) if the cancer rates were as those observed in the specified time period in the absence of competing causes. Like the age-standardized rate, cumulative risk permits comparing between populations of different age structures.

Incidence. Incidence is the number of new cases arising in a given period (usually a calendar year) in a specified population. It can be expressed as an absolute number of cases per year or as a rate per 100,000 persons per year (see age-specific rate and rate above). The rate provides an approximation of the average risk of developing a cancer in a population for the time period of reference.

Mortality. Mortality is the number of deaths occurring in a given period in a specified population. It can be expressed as an absolute number of deaths per year or as a rate per 100,000 persons per year.

Percentage change. The percentage change compares two age-standardized rates (ASR): the rate of the selected country with the rate of the selected reference (Europe or EU28). The formula is (ASRcountry-ASRreference)/ ASRreference. For example, a relative change of +5% indicates that the country rate is 5% higher than the selected reference rate. Similarly, a relative change of -10% indicates that the country rate is 10% lower than the selected reference rate.

Population at risk. The part of a population which is susceptible to develop a specific cancer. It is defined on the basis of demographic data, such as place of residence, sex, age group, etc. Years of risk duration are counted in person-years.

Relative survival. The relative survival is a standard indicator for comparing cancer survival in population-based studies when the underlying cause of death in unknown. Relative survival is the ratio of the observed survival of patients to the expected survival in a comparable group in the general population for the same region, age, sex and calendar year. It can be interpreted as the survival probability of cancer patients in the absence of other causes of death, which can vary widely between countries.

Standardized incidence and mortality rates represent fictive values reached by a certain technique, introducing standard population: usually World (ASR-W), European (ASR-E) or truncated population (ASR-TRUNC). They are used to eliminate differences (mostly gender and age) existing in different populations and are, therefore, convenient for comparing.

Survival or Observed survival. It is the probability to survive after a given time from diagnosis (1,3, or 5-year), regardless from the cause of death. Observed survival probability is influenced by mortality due to cancer and to other causes of death. In international comparisons of cancer survival the effect of causes other than cancer, which can vary widely by countries, is removed by using relative survival.

4.8 Technical Requirements

4.8.1 General Requirements

4.8.1.1 Simultaneous execution

The CR-IS information system should enable simultaneous login as well as concurrent work for a minimum of 100 people. Increasing the number of concurrent users should not affect the system's performance.

4.8.1.2 Response and load times

It is expected from the contractor that the page of CR-IS web application loads for no longer than 2 seconds, on average.

4.8.1.3 Openness and scalability

Technical requirements concerning openness and scalability of IT systems imply that the system must have the characteristics of an open system, and it has to be easy and simple to expand. The requirement for simple and easy expandability of the system must be taken into account when designing a database, as well as all the software modules.

4.8.2 Security

4.8.2.1 Basic security requirements

CR-IS information systems will provide secure connection between the system and the end users, as well as with external information systems via services. It is expected for CR-IS to meet following security requirements:

- Confidentiality - it is necessary to provide secure communication channels between:
  - the CR-IS information system and the end users
  - the CR-IS information system and external information systems (via services),

  by using encryption for all messages that are exchanged between them. Implementation of encryption shall be achieved with appropriate implementation of HTTPS/TLS (for external information systems which will exchange data with the CR-IS information system via web services, in accordance with the capabilities of an external information system) or by using another protocol for secure communications in cases where the external information system does not support the Web services.
- Data Integrity - the system must ensure integrity of data during their transmission through the communication channel,
- Authentication and authorization - the system must determine the user's identity and the right to access the requested resource using 3rd party service (Batut authentication and authorization service).
- Non-repudiation - the system must ensure that the participants in the communication cannot subsequently deny their participation in communication with CR-IS by using a digital signature technique.
- Audit - the system must record each access to a resource or an unauthorized attempt to access a resource. The log record must at least include the access time, IP address and username (if available).

4.8.2.2 Security of the CR-IS system segments

All system segments (servers, virtual machines, network devices, etc.) of the IT infrastructure of the CR-IS information system must also be secured in an appropriate manner, using different techniques, and at least:

- hardening of the operating system,
- application of strong password policies,
- application of ACL (*Access Control List*).

In addition, it is necessary to provide a system of supervision of all segments of the CR-IS information system, as well as applicative, service and hardware.

Likewise, the application of appropriate security principles is very important and must at least be applied to the following two:

- principles of minimalism and
- principle of duty separation, of both users and administrators, as well as system services of the CR-IS information system.

4.8.3 Methods to access the CR-IS information system

There shall be two ways to access the CR-IS:

1. Web access, i.e. access via web app - by the end users of the system. Application of appropriate security mechanisms on Web applications and the Web / application server on which the application is executed shall provide, in this case, defined security requirements.
2. Access via Web services - by external information systems. In this case, the security requirements shall be achieved by application of mechanisms for ensuring security of Web services.

4.8.4 Monitoring of the CR-IS information system

Critical components of the IT infrastructure of Registry including network, system and application services, physical and virtual servers, and network nodes should be continuously monitored. Minimum requirements which monitoring must meet are:

- Ability of sending information about problems that occur in critical components of the IT infrastructure of Register. Submitting this information should be provided through various channels, at least through the Web and e-mail, and optionally by SMS.
- Ability of creating various reports, and minimally reports of unavailability of critical components of the CR-IS information system's IT infrastructure, generated by events and notifications.

4.8.5 Data management requests

Data storage of the CR-IS information system should be based on a relational database management system. In particular, the choice of relational database management systems should allow easy migration of data from a database of a relational database management system that uses current implementation of CR-IS.

Database management system should, as a minimum:

- support parallel execution, with no restrictions on the functions of selecting, adding, deleting and modifying data,
- have efficient memory management,
- support online backup and restore options,
- support client / server architecture, including:
    - separation of the end-user interface and DB,
    - ability to send remote queries,
    - ability to remotely update the database,
    - multi-user access with reliable access control
- work on a platform that is specified in this document,
- support ANSI Structured Query Language (SQL),
- import and export data from / to various standard formats, including at least two major DBMS formats:
    - sequential ASCII format
    - budget (spreadsheet) format
- transaction logs and events
- commands for execution and return to the old status for each work unit (*Commit and Rollback for a unit of work*)
- locking at the level of table, row, and page (table, row and page level locking)
- distributed and parallel queries (distributed and parallel queries)
- multiple indexes / Multiple Indexing (multiple indexes)
- transactional replication (duplication) of data while ensuring data consistency and methods (procedures) to resolve conflicts that arise during replication (data replication with transactional consistency/conflict resolution features)
- query optimization (query optimization)
- data storage with automatic generation of summary statistics for management and their analytical processing *(data warehousing summary management/auto-statistics, analytical processing*)
- triggers (*triggers*) which are automating appropriate procedures within the database
- ensure referential integrity, cascading deleting and deletion restriction (*declarative referential integrity and delete cascade/restrict*) - a series of procedures that ensure data integrity
- support for graphical user interface (GUI) front-end and Forms / Queries / Reports (support for
- Graphical User Interface (GUI) front-ends and Forms/Queries/Reports)
- Support for long variable text fields (support for long text fields)
- support for Unicode standard (Unicode support)

For all of the data stored and processed by the CR-IS information system there must be an appropriate procedure for export and imports as well as a formally defined format for import / export, which must be simple and standardized.

For all of the data stored and processed by the CR-IS information system there must be an appropriate procedure for export and imports as well as a formally defined format for import / export, which must be simple and standardized.

4.8.6 Reporting requirements

The reporting facility must be able to create reports based on data entered into the system; and there must be the ability to add new reports. It must be possible to create a new design of reporting data structures for each business year. There must be a transformation method that will enable comparability of reports from year to year and in the case of redesign reports.

4.8.6.1 Report types

The enhanced CR-IS information system should facilitate work with two types of reports:

1. predefined reports and
2. on-demand reports (ad-hoc reports).

Predefined reports mean statements that are created according to pre-specified criteria and time periods / intervals given in advance.

On-demand reports are created as needed and are not created in predefined time periods / intervals. With this type of report, the criteria for generating reports are set just before generating these reports, as appropriate. On-demand report results should be displayed with the help of advanced graphical representations such as side-by-side comparisons of different colors, columnar, dotted, line shapes, speedometers that effectively display deviations from reference values, etc.

Both predefined reports and reports at request must have the ability to filter data according to set parameters.

4.8.6.2 Report formats, and presentation style

Each report as a minimum must be available in the HTML format, and allow displaying / printing reports to PDF format. Reports should be possible to export to other standard formats (depending on context):

- Text format - CSV (txt)
- JSON format,
- MS Excel / OpenOffice Calc format
- standard image formats (png, jpg, ...)

According to methods of presentation, creation of the following types of reports should be enabled:

- reports with tabular presentation - data is shown in tables,
- reports with the presentation in rows - each data (entity) is shown in a single row,
- reports with graphical presentation - numeric data are presented on a graph with appropriate labels. It is necessary to enable the creation of different types of charts (pies, bars, lines ...).

- reports with presentation on the map - a numerical and / or graphical data are presented on a simplified map of the Republic of Serbia which contains municipalities and cities. In addition, except a simplified map it is also possible to use the existing projects for work with maps (eg. OpenStreetMap), for data presentation.

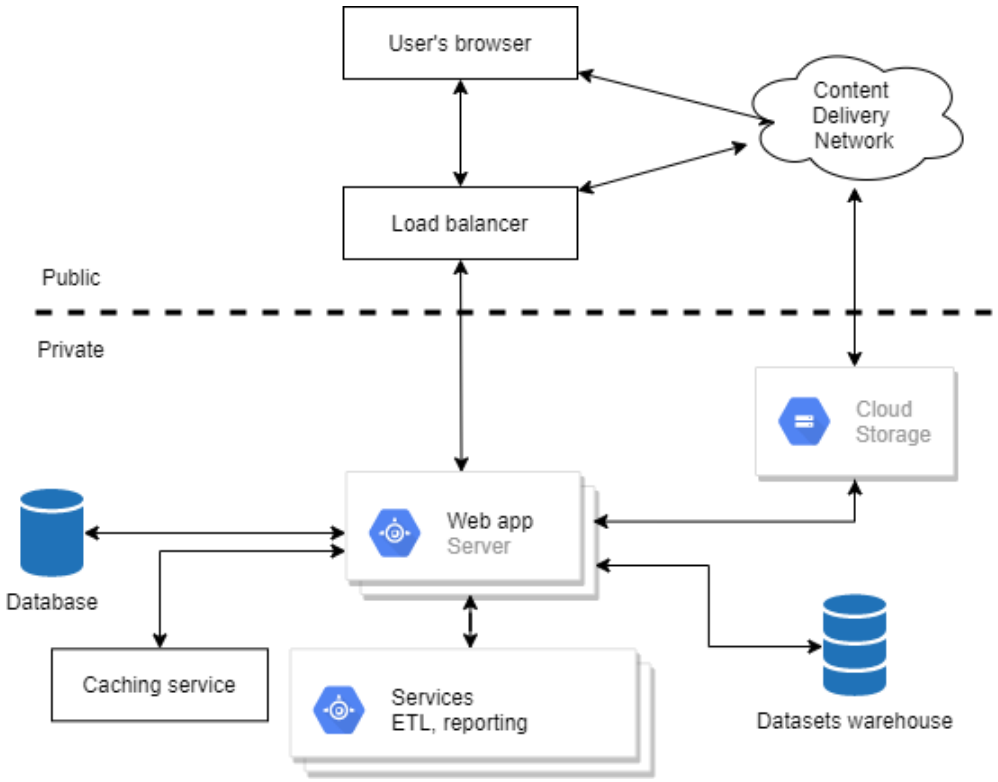
Reports should be formatted so that their presentation is correct on screens with different resolutions, and so that they are correctly printed on standard paper formats, and must be in A4 format with horizontal and vertical orientation.

5 TECHNICAL SPECIFICATIONS

This chapter provides the technical specifications of the system platform components. However, it is important to notice that Contractor is not expected to provide physical hardware (servers and workstations, communication equipment) but rather only virtualized components of the system platform.

5.1 System Architecture

The system necessary for the implementation of the Cancer Register information system implies the existence of appropriate communications equipment, servers and workstations. Following configuration is suggested system architecture of the Cancer Register information system and proposed configuration builds on requirement for single page app (SPA).



5.2 Network Architecture

Access to the CR-IS information system will be implemented through the Internet. The connection to the Internet should be provided through two firewall devices operating in failover configuration. The CR-IS must have at least one public IP address that will maintain access to the CR-IS application and web service. The firewall has to be configured in a way that the public IP network only has access to the CR-IS application and Web service. It is important to notice that the State Data Center is going to provide server hardware and network infrastructure resources, so Contractor should communicate and investigate the Office of Information Technologies and eGoverment terms and conditions for deployment and achieving operational status for the software solution.

Servers and firewall devices have to be connected to the switches through a minimum, 1Gbps ports. The switches also have to be configured to operate in a failover mode.

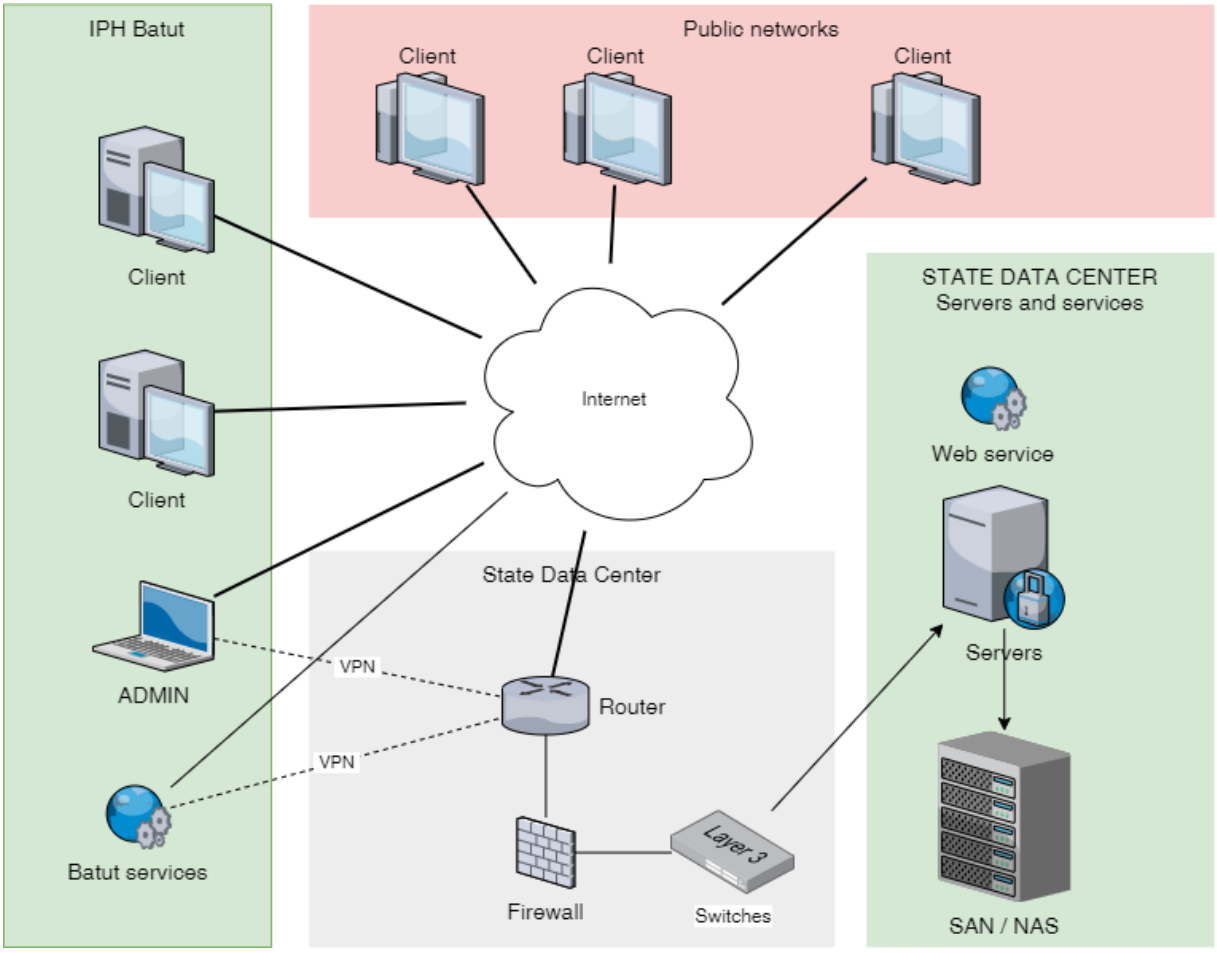
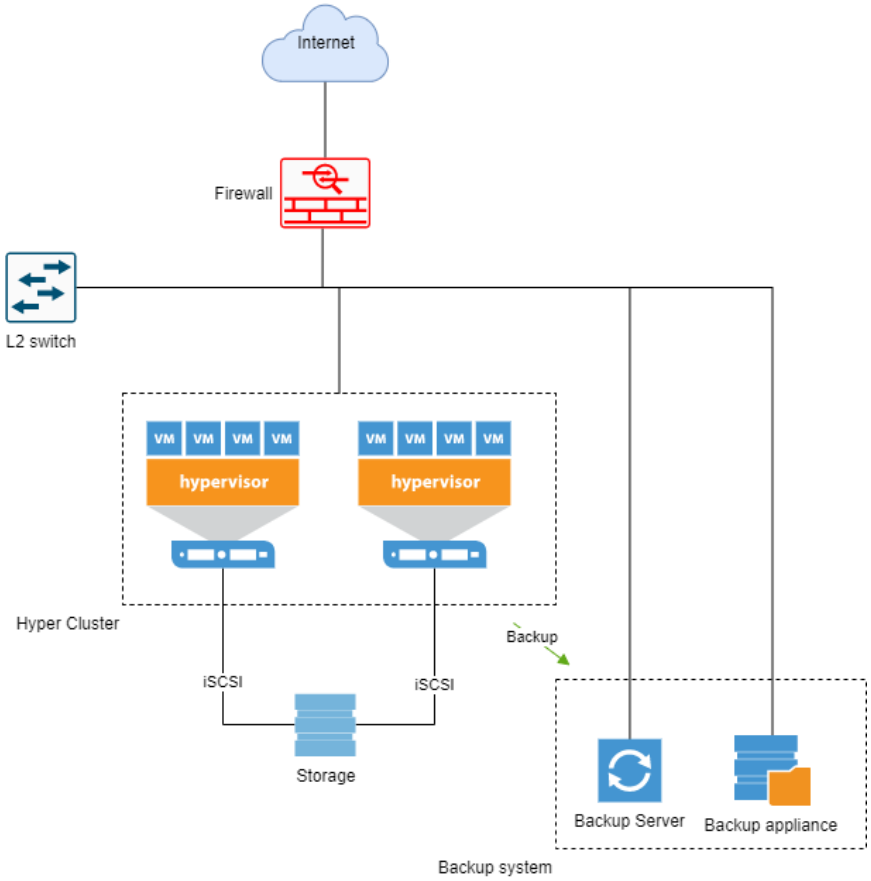


Image shows a rough diagram of the system on which the following hardware components: (1) router (2) firewall(s), (3) switches, (4) servers, (5) SAN/NAS, (6) workstations. The State Data Center shall provide server hardware and communication infrastructure for operational deployment of the Cancer Registry.

5.3 System Platform

Software solution should be deployed on virtual machines in a cluster failover configuration to provide high availability. Virtual machines will be executed within two virtualization servers that will be in a cluster configuration.

Physical servers shall be connected to the SAN / NAS platform, where virtual machines will be located. It is preferable that the virtualization software supports live migration of virtual machines between nodes and clusters.



Proposed deplyoment platform

The virtualization platform should meet, at least, the following requirements:

- Hypervisor has to be based on the Intel VT or AMD virtualization technology;
- Support for full virtualization, ie. to support hardware-assisted virtualization. The feature has to be supported regardless of the operating systems of the virtual machines;
- Supports various user operating systems (operating systems of virtual machines) minimum current Windows server OS and popular Linux distros server operating systems;
- has a graphical user interface for management and administration;
- supports live migration of virtual machines between clusters of nodes;
- supports creating backup copies of virtual machines and restore them;
- has support for SAN / NAS (Storage Area Network / Network Area Storage);

- has a support for virtual machine templates, i.e. creating virtual machines based on pre-given patterns;
- has tools for the management of storage devices;
- provides transparent access to a storage by virtual machines.

5.3.1 System software of virtual servers

On virtual servers, a stable server operating system must be installed. Operating systems have to be licensed (proprietary or open-source).

Virtual servers should have adequate anti-virus protection.

Virtual servers need to have installed and configured firewall software. It is necessary that only necessary ports are open and only the necessary software installed.

It is necessary to enable remote access and administration of virtual server operating systems, but only with pre-defined locations (address space).

Servers must be time-synchronized with a reliable source of accurate time.

Operating systems have to be up-to-date; a strong password policy must be applied.

5.3.2 System software for backup

The system for backups should create backups of a virtual server on a virtualization layer that requires backup applications designed and optimized for virtualization.

The application should create a backup copy of the disk file virtual server.

The consolidated backup should offer the following features:

- executes a secure process backup on a dedicated physical host,
- requires no backup agents on virtual machines,
- does not limit the use of Fiber Channel tape,
- supports backup on file level,
- supports backup at the "virtual server snapshot" level for any operating system,

Backup applications should support a temporary pausing of a virtual server.

When a virtual server is paused, a snapshot of the virtual server should be made before the backup. The application should allow data deduplication (eliminating duplicate blocks of data stored in the backup repository) and data compression (compress the data in the backup repository so they take up less space).

Instant file-level recovery should be supported so that individual files can quickly be restored to any point in time of backup and restoration at the application level.

It is necessary to implement a Universal Application-Item Recovery that allows recovery and restore of individual application items that were accidentally deleted or corrupted.

The Administration Console should be user friendly and allow the administrator control through a web interface. This should provide the administrator to implement functions of backup on any server or internet / Java client with a supported web browser.

The software should support the notification of the event to inform the administrator about backup cases such as "Operation failed" or "discontinued operations", etc.

The software will offer a centralized management console for backup.

The software will support an online backup database and OS.

It will offer software licenses for backup of a defined system.

Licenses for backup software should correspond to a given servers-storage system, and the total number of processors / cores.

5.4 Physical placement

The Office of Information Technologies and eGoverment of the Republic of Serbia Government shall provide hardware and communication resources for the the Cancer Register Information System of Serbia. The CR-IS shall be deployed in the State Data Center. The Center meets the Tier 3+ standard, and the Center's services are provided in accordance with the ISO 27001 security standard, ISO 9001 quality standards, as well as with the quality of service provision, ISO 20000.

Resources in the Data Center are offered to the State Authorities according to the IaaS (Infrastructure as a Service) model, i.e. virtual server resources are issued in accordance with the user’s request. This model implies that all infrastructure, i.e. hardware components, including the virtualization layer, is hosted in the State Data Center.

The Contractor shall prepare all necessary documentation per request of the Office of Information Technologies and eGoverment needed to facilitate the deployment and, later on, operations of the CR-IS. The Contractor shall adapt configuration parameters of the software solution to inputs received from the Office. In addition, the Contractor, as early as possible, however not later than integration testing, shall provide hardware / virtualization requirements to the Office so that the Office can dedicate hardware / virtualization (processor, memory, hard drive and storage) and communication capacity (bandwidth) necessary for optimal work of the software solution on planned number of users.

6 IMPLEMENTATION FRAMEWORK

6.1 Institutional arrangements

6.1.1 Communication

The Contractor shall cooperate directly with (1) appointed representative of the Second Serbia Health Project and (2) Beneficiary's Project Team who will be the source of needed information. The Institute shall enable access to the documentation sought by the Contractor, but processing of Institute's documents and documentation is obligation of the Contractor.

Prior to the commencement of each phase, the Contractor shall present what is to be done in the phase which is commencing and what the status of the project implementation is at the time. The activities cannot commence before both representatives give its consent.

The Institute may decline to give consent for further implementation of activities, if the proposed solutions are contrary to the project documentation, business or strategic documents and rules of the Institute.

6.1.2 Meetings site

Key meetings, activities related to the familiarization with the existing software, organization, the methods of work of the Institute, considerations related to software development, and presentations will take place in the Institute of Public Health of Serbia headquarters.

The Contractor is responsible to arrange its own logistical matters that is the transport, lodging, per-diem and travel expenses.

6.1.3 Reporting

The Contractor shall regularly, on a 15-day basis, report to the (1) representative of the Second Serbia Health Project and (2) Beneficiary's Project Team (the Institute) on activities performed, possible problems in work and all elements necessary for a successful implementation of the Project. If necessary, and in particular, on possible deviations from the planned dynamics of the project, Contractor can be asked to different reporting periods as well.

The report shall be submitted in written form, via electronic mail. In case they deem it needed, the representatives may ask for extra reports with specified elements, or may define a structure of regular reports, which the consultant is obliged to accept.

6.1.4 Software testing

The testing of developed software will be done jointly by the Institute representatives and the Contractor. Should the Institute conclude that there is a need for it, the Institute may hire an independent consultant or organization to test the software.

6.1.5 Software and source code ownership

The Contractor shall submit the complete source code base for the applicative software, library and frameworks used by the software, deveoped by the Contractor. The Institute of Public Healht of Serbia shall possess the software and source code ownership rights, to use them at its discretion, and in accordance with the Law on Copyright and Similar Rights of Republic of Serbia.

6.2 Project Management

The Contractor is expected to develop and submit a detailed plan of project implementation, and to provide adequate human resources for its implementation.

The contractor is required to use agile based project methodology, or any similar methodology that will allow regular and frequent insight for domain experts and project sponsors on proposed technical implementation.

The Contractor, at the beginning, shall present a project management instrument which will be used to track progress (project management software or other tool(s)), and provide training and instructions for its use to the Client's Project Team, if necessary. In addition, the Contractor shall present a tool for reporting errors and objections of the users, which will be used for more efficient communication and documentation of important events during the implementation and testing phases (i.e. during the iterative repetition of these phases). The Contractor must perform the tasks in accordance with the time limits as contracted, or in case of subtasks as defined by the Client's Project Team.

Any changes based on the requirements generated during the system analysis, design and development phases can only be included in the solution through change request process, with consent of the Client's Project Team.

The contractor must describe at the beginning of his work his adjustment process and how it will be applied, giving one practical example of a functional request, providing details of the approach he will apply.

6.3 System development

The Contractor shall present at the beginning sufficiently detailed preliminary project plan showing the structure of the division of work and the order and timeline for each activity. The plan must contain the proposed configuration of assignments by executors with the numbers, roles and responsibilities of team members, schedule of activities, by items, and start and end dates. The plan must have a practical division into the stages of analysis, design, development, testing, acceptance and post-implementation support for the Software solution. In addition, the project plan must provide such access to installation and testing that will ensure the quality of the results of the software system.

The project plan must give frequent opportunities to Contactor's Project Team to review and verify the Contractor decisions before being actually developed and implemented.

The project plan will be aligned with the actual realization of activities and agreed upon with the Client's Project Team.

At the end of the project implementation, the Contractor must provide a turnkey delivery for the scope of functionality defined during the project preparation and final design stages.

6.3.1 System analysis

The Contractor is expected to perform system and user requirements analysis using structural system analysis (SSA) methods and to create a complete specification of the information system. In particular, the contractor should produce a hierarchically organized set of data flow diagrams, data dictionary and a specification of logic of the primitive processes.

At the beginning of the project, Contractor and Client's Project Team shall clarify in detail user requirements, and confirm what belongs and does not belong to the the application solution. The agreement on the domain and minimal viable product on the extent of functionality that will develop immediately and those that will be subject to future development phases shall be clearly defined.

The Contractor will adapt recommendations from these terms of reference accordingly.

6.3.2 System design

Contractor is expected to find the optimal design solutions to meet the user requirements defined in the phase of system analysis. Design has to be approved by Client's Project Team before actual coding and construction of the software starts. The system design should include at least:

1. design and documentation of the application architecture and application modules prototypes (menus, screen dialogs and masks, reports, batch and manual procedures, user groups, design of interfaces for screens and reports)
2. design and documentation of the database (selection of implementation techniques for entities, database normalization, analyzing performance, size of tables and need for access, add indexes, conduct optimization of spatial consumption, adjust the design according to the needs of distribution, defined user views on the database, perform the initial filling of database)
3. design of communication and network architecture (network topology, network flow, standards, user plan, server configuration, ...)
4. security design (confidentiality, integrity, authenticity, non-repudiation, availability, audit, authentication, reliability),
5. design of backup and recovery procedures (documentation, compliance with standards, ...).

6.3.3 System construction

Contractor shall start implementation / coding – actual construction of software – once the Client's Project Team confirm the Design document. Software components shall be implemented as defined in the Design document.

6.4 System integration

The Contractor is expected to perform full system integration. Basic phases of system integration are:

1. installation, configuration, testing and putting software solution into operation,
2. installation of system and middleware software, database management software, application servers, etc. and their configuration, testing and putting into operation
3. installation of application software and its configuration, testing and putting into operation
4. migration of existing data from an existing cancer register databases to the new CR-IS.

6.5 Cooperation with healthcare institutions' software providers

CR-IS should collect as much as possible data that is being entered only once. For hospitals which have its own hospital based cancer registries or they utilize hospital information systems that meet data requirements specified in the reporting form it will be necessary to create interface for automatic data exchange and import.

Contractor shall provide necessary instructions and technical documentation how CR-IS API is going to work, and what resources shall be provided by CR-IS to vendors that have software solutions deployed in health facilities in Serbia. Contractor will provide the information as soon as possible, so that the software providers can make upgrade of information systems and rollout early enough.

Client's Project Team will facilitate communication with software providers via hospitals.

6.6 Data Migration

The Contractor is obliged to migrate and transfer all data from Cancer register database situated in Batut;

Integrity of migrated data must be preserved. Incomplete, inaccurate or duplicate data must be identified and corrected during the process of data migration. Contractor shall migrate data, codebooks and datasets with minimally taking care of:

1. Convert System Definition file(s)
2. Query user with regard what table the different variable should be stored
3. Clean the data if non-standard
4. Normalize dictionaries
5. Normalize population data sets

For data migration, the Contractor is required to apply methodology that will ensure:

1. data integrity,
2. detection of errors,
3. mechanism for correcting transmission errors,
4. mechanism for reparations of original data quality,

5. transformation of data according to the requirements of the target (improved) system,
6. reporting on the data that are transmitted, as well as the data which aren't transferred,
7. validation of transferred data,
8. possibility of returning to the state prior to the migration process,
9. repetition of the entire process per request, or its parts,
10. that complete data transfer process is controlled and manageable,
11. that the impact on business processes be minimal.

6.7 Software solution support after the delivery

Contractor shall provide support to end user after handover. Only warranty shall be included in this contract. Technical support to end-users and software maintenance are not part of this contract, however Contractor is obliged to provide a guarantee for provision of technical support to end users and maintenance services in post project exploitation, if such request comes from Beneficiary.

Maintenance and end user support will be regulated by separate support and maintenance contract (service contract). Contractor shall give a proposal for maintenance and end user support. Beneficiary can decide to accept the proposal, request changes and amendments or reject it at its full discretion.

6.7.1 Warranty period

The warranty period starts from the handover date of the Software solution.

The Contractor is required to maintain functioning of the Software Solution as designed for a period of twelve months.

All problems with the system functions and performance that affects work of the system Contractor shall fix free of charge during warranty period.

In the case of system failure, the Contractor is obliged to bring the system into a functional condition, in the shortest possible time. If the system is functional, but there are some problems in its functioning, the Contractor shall remove the problems within 7 days from the time of the problem reporting.

In case that period to fix an error exceeds one week, the warranty period shall be extended for such period.

6.7.2 Technical support

Contractor shall provide support to end users of Software Solution after the handover of the system if a support contract is signed. The end users will send requests for support to the Contractor through a help desk application provided by Contractor, in order to have track of all the request and responses/ resolutions.

The Contractor is obliged to provide timely and adequate technical support that may be provided in different ways, as follows:

1. by telephone - the response time for providing this kind of support from the moment of reporting the deficiency is 30 minutes
2. e-mail - the response time for providing this kind of support from the moment of reporting the deficiency is 120 minutes
3. remote access – the response time for providing this kind of support from the moment of reporting the deficiency is 180 minutes
4. arrival at the location – the response time for providing this kind of support from the time of reporting the deficiency is 24-hour.

The specified response times are valid during the working week, in the time in which the end users effectively uses the information system.

Duration of obligatory technical support

The Contractor is required to provide technical support upon completion of the project for a period of at least 5 years.

6.7.3 Software solution maintenance

The Software Solution maintenance should keep it operational and relevant against its business goals. Maintenance for purpose of this project encapsulate:

- Corrective maintenance: changes to software solution as requested by end user, with aim to remove identified problems;
- Adaptive maintenance: changes to software solution as requested by changes in business environment, with aim to keep the solution relevant in changed environment;
- Perfective maintenance: changes to software solution in order to improve performances, usability, functionality and user experience;
- Preventive maintenance: modifications of software solution in order to prevent latent errors before those errors can bring software solution to halt or break.

Duration of obligatory maintenance

The Contractor is required to provide software solution maintenance upon completion of the project for a period of at least 5 years.

6.8 Training

Contractor is obliged to provide adequate training, for:

1. End users of the CR-IS in institutes for public health. As there are 24 institutes for public health and the Batut Institute, this segment of training will be attended by about 80 users. Due to the large number of participants, it is proposed to organize training on a regional basis.
2. End users of the CR-IS information system in the Batut Institute. This segment of training will be attended by expected five (5) users.

3. Technical staff (administrators) who will be responsible for the administration of the CR-IS information systems and related equipment. This segment of training will be attended by expected five (5) users. It is recommended that the training of administrators be conducted at a central location at which CR-IS will be implemented.

User training should be prepred as hands-on lab. Contractor will prepare a set of scenarios where users will learn capabilites through solving tests scenarios. Test scenarios should cover all planned uses of the CR-IS in process manner – from data entry (form submision) to case analysis and data analysis.

Contractor should provide video training as well.

All training programs must have a documented curriculum and defined goals, that is, a minimum satisfactory level of training.

Should the Institute of Public Health of Serbia require it, the Contractor must provide certificates of completed training.

Contractor training instructors should have proven experience in their fields. Instructors must be approved by the Client's Project Team before undertaking any training.

Contractor must provide training materials in electronic form to enable institutes of public health to conduct trainings and transfer knowledge independently after the implementation of the project.

6.9 Documentation

The Contractor is expected to deliver:

1. end user documentation and
2. technical documentation, as follows:
    a. documentation of derived state, and
    b. documentation intended for system administrators.

The Client shall reserve the right to copy, duplicate, alter and use the documentation as whole or in parts without any additional costs and/or restrictions.

All documentation shall be prepared in Serbian language.

6.9.1 End user documentation

Documentation intended for end users shall consist of (1) manual for operation and use of the information system and (2) built-in help subsystem within the application. The electronic version of the manual should be up to date and keep track of all changes to the application software and should be accessible from within the web application.

The built-in help subsystem shall provide end users with a context based step-by-step user guide with screenshots of all the actions with necessary explanations, as well as an available video guide for key actions.

Contextual help must be provided for each window and input fields. System should have functionality that will allow an administrator or the role to which such a right is granted to maintain such explanations.

6.9.2 The Software Solution Technical Documentation

The technical documentation of software solution should include a detailed description of the system, installed hardware, software and network connections (physical and logical) that corresponds to the final operational state.

The document of derived state should include a detailed description of the system, installed hardware, software and network connections (physical and logical) that corresponds to the derived state. The document of derived state can be realized through a number of documents, which comprise specific logical units of information system (network, storage, servers, software ...). The documentation must be available both in hard copy and in electronic form, including the following:

1) application design specifications,
2) technical specifications of the system,
3) document on the system infrastructure,
4) document on application modules,
5) document on the operation and maintenance of the system.

The technical specification will include, but will not be limited to:

1) current list of reporting units and items,
2) linking report items to predefined static reports (in the previous system to individual sheets in the Methodology),
3) mapping of reporting categories with coding categories and ICDs,
4) a detailed textual description of each item (what is covered and what is not),
5) a list of dimensions for OLAP structures, each with explanations,
6) list and description of analyzes available to the institutes of public health on the basis of OLAP structures,
7) all codebooks with explanations of individual values where needed,
8) mapping the values that are the basis for creating binding tables,
9) data model including relations for relational database,
10) description of elaborated business process with graphic representation (BPMN or some other notation),
11) description of input forms, user menus and options,
12) a graphical representation and description of the software of the software solution,
13) a graphical representation and description of the system infrastructure, detailing all the servers and technologies to be used,
14) specification of security solutions according to set requirements.

The infrastructure system document will include, but will not be limited to, the following:

1) presentation of the architectural environment,
2) platform configuration,

3) configuration management,
4) system crash recovery and business continuation plan,
5) operating manual.

The Application system document will include, but is not limited to, the following:

1) description of the installation,
2) the structure of the database / database,
3) application controls,
4) interfaces to other systems,
5) security control matrix,
6) privacy control,
7) integrity control,
8) backup and recovery operations, etc.

The system maintenance document will include, but will not be limited to, the following:

1) maintenance schedules and procedures,
2) configuration management plan,
3) detecting and troubleshooting including a list of error messages,
4) performance tuning and capacity planning,
5) security management,
6) backup and recovery procedures.

Load testing document will include:

1) load testing methodology, description of the process of measuring performance and adjusting application software.

Security testing

1) documentation on the testing methodology, deployed tests and results of testing; in addition, if a security breach was identified adjusting the software solution.

Technical documentation must be delivered in electronic and printed form, in Serbian language.

6.9.3 System administration documentation

Documentation intended for system administrators should include materials necessary for CR-IS information system administration and for day to day operations of the software solution with clearly laid out operational procedures.

The number of printed manuals is to match the number of training participants, and manuals need to be prepared in Serbian language. The electronic version of this manual must be up to date and keep track of all changes to the application software.

6.10 Quality Assurance

The software solution shall be subject to software quality assurance beyond standard development testing. A quality reference model shall be used to ensure that developed software meets and complies

with requirements laid out in terms of reference. Software quality assurance shall be an ongoing process within the software development life cycle, and Contractor will be obliged to demonstrate that the developed software solution meets desired quality measures.

The software solution must be verified against quality assurance model with countable and repeatable metrics, before it can be accepted and handed over to the final beneficiary. The Contractor can propose different quality assurance model for which it believes it better reflect nature of the software solution. Client's Project Team shall participate and agree on final proposed quality assurance tools and methods.

For such purpose, a reference standard model to evaluate quality of software solution shall be used (adopted from ISO/IEC 25010:2011), if no other model is specified.

6.11 Testing

6.11.1 Pre-commissioning test

The Contractor is expected to create a test environment for information system. The test system must have all functionalities of the production system, and it is primarily necessary to enable:

1. test Web application of the information system
2. test Web services of the information system with external information systems,

The Contractor is expected to submit a plan for testing the Web application of the information system and the system integration testing plan, which involves testing scenarios for all functionalities defined in the technical part of the tender documents. The test plan will be reviewed and approved by a team consisting of representatives of the users of the system and adjust it with the contractor.

The Client's team of representatives will, supported by Contractor, carry out individually testing of all functionalities of the information system, including testing of all functionalities of application part of information system, network, communication and the system part of the information system (backup, restore, live migration of virtual machines, etc.). This part of testing shall be conducted using user stories methodology.

All deficiencies discovered during testing will be documented, while the Contractor has an obligation to remove them as soon as possible, and before conducting the test of acceptability.

6.11.2 Operational acceptance tests

The Contractor will together with a team consisting of representatives of the users of system, conduct acceptance test of CR-IS information system.

The system performance measurement prior to acceptance will be performed on the basis of a representative sample of processes to be defined by the Client's Project Team.

The minimum requirement for acceptance of the system will be to achieve at least the volume of reports and analyzes that exist in the current system.

6.11.3 Security tests

The Contractor will, together with a team consisting of representatives of the users of system, conduct a security testing and penetration testing that will involve at least:

- Network security: vulnerabilities in the network infrastructure (resources and policies).
- System software security: assessing weaknesses in software (operating system, database system, and other software) the software solution depends on.
- Client-side application security: ensuring that the client (browser or any such tool) cannot be manipulated.
- Server-side application security: ensuring that the server code and its technologies are robust enough to fend off any intrusion.

Contractor will perform security tests in line with recognized testing frameworks. Open Web Application Security Project (OWASP) testing methodology will be used in case that Contractor does not propose different security methodology. Final proposal for security testing shall be subject to previous approval by Client's Project team.

6.12 The system handover

The handover of the system is conditioned by passing battery of tests defined in section 6.14 Testing, and scoring positively on quality assurance review as defined in 6.13 Quality Assurance.

No handover shall be committed as long as the software solution is cleared against defined tests and quality assurance measures – i.e. no warranty period can start no matter if the Contractor declares software to be operational in production version.

6.13 Implementation period

The expected implementation period of the project is seven months.

Following the handover of the CR-IS starts a warranty period for one year.

The information system maintenance after the expiration of the warranty period will be governed by a separate agreement.

6.14 Implementation schedule

The implementation schedule sets up general timeframe for activities during the implementation of the project, along with the locations where the activities should be implemented and the expected implementation period. The implementation schedule shall be amended in case Contractor is not allowed full access and support to all necessary locations and systems. In this case, the expected time of implementation is prolonged for the standby time.

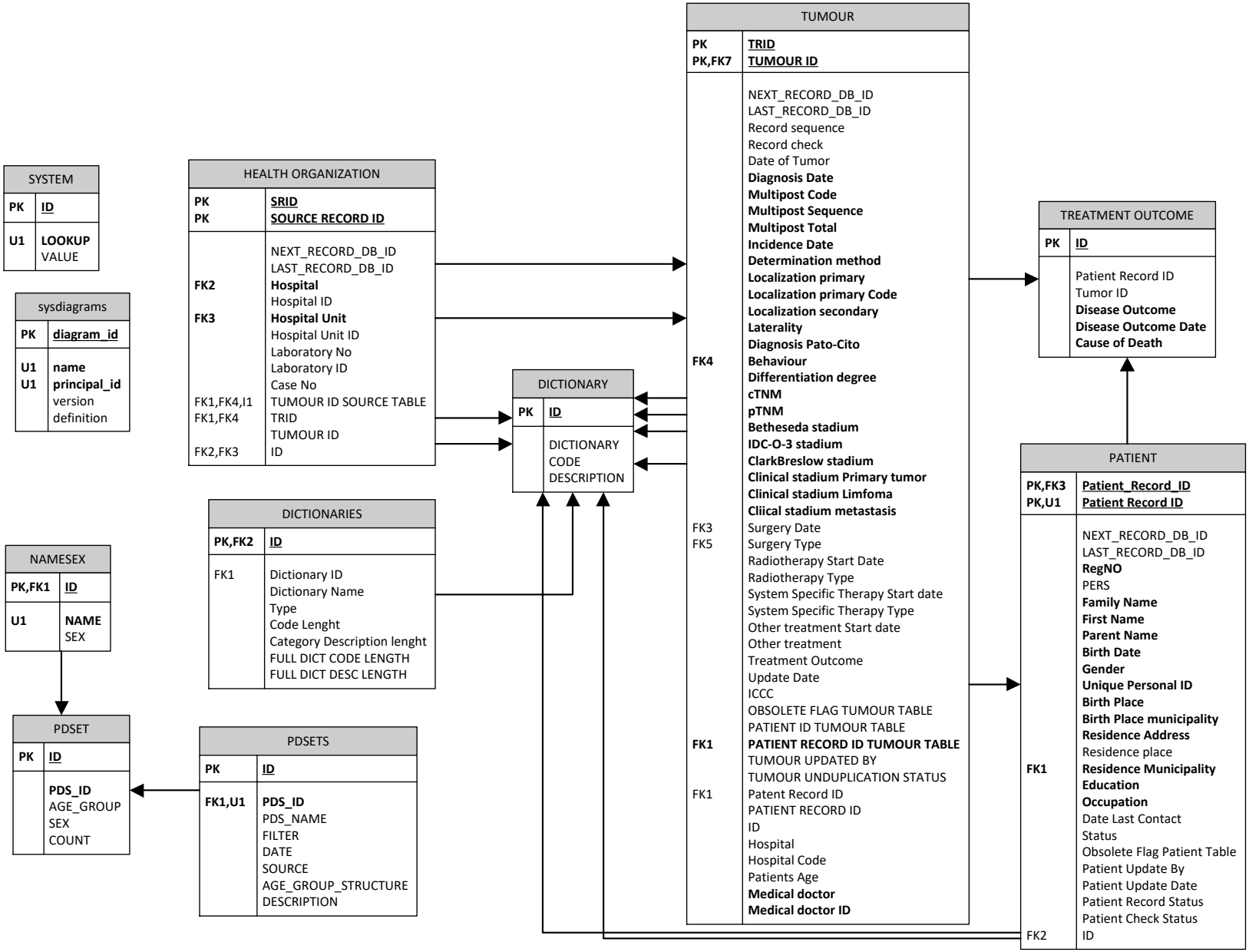
Line Item No.	Subsystem / Item	Configuration Table No.	Site / Site Code	Delivery (Bidder to specify in the Preliminary Project Plan)	Commence-ment (days from Effectiveness)	Acceptance (days from Effectiveness)	Liquidated Damages Milestone
1	Project Plan development		Contractor		2	12	No
2	**Phase 1 – Technical Design**						
2.1	Review and analysis of the existing systems		IPH Batut		13	18	No
2.2	Requirements Analysis and Development		IPH Batut		13	18	
2.3	Review and acceptance of the requirements		IPH Batut		18	20	
2.4	Cancer Register design development including interface and web services		Contractor		21	28	No
2.5	Cancer Register design review and acceptance		IPH Batut		28	30	No
2.6	System Design Development		Contractor		31	41	Yes

Line Item No.	Subsystem / Item	Configuration Table No.	Site / Site Code	Delivery (Bidder to specify in the Preliminary Project Plan)	Commence-ment (days from Effectiveness)	Acceptance (days from Effectiveness)	Liquidated Damages Milestone
2.7	Review and acceptance of the system design		IPH Batut		42	46	
2.9	Acceptance of Phase 1		IPH Batut		47	49	
3	**Phase 2 – Development, Deployment and Customization**						
3.1	Development of the core system, including interfaces and web services (80% of the system developed)		Contractor		50	100	Yes
3.2	Review and analysis of Beta Version of the Systems		IPH Batut		101	110	No
3.3.	Acceptance of Beta version		IPH Batut		111	118	No
3.4	Development of all modules (100% of the development and upgrade)		Contractor		119	150	Yes
3.5	Review and analysis of Release Candidate version		IPH Batut		151	158	
3.6	Testing & Final Customization of the final version		Contractor		159	169	No
3.7	Deployment, data migration, configuration and delivery and adjustments and replacement of existing Cancer Registry software		State Data Center		170	175	Yes

Line Item No.	Subsystem / Item	Configuration Table No.	Site / Site Code	Delivery (Bidder to specify in the Preliminary Project Plan)	Commence-ment (days from Effectiveness)	Acceptance (days from Effectiveness)	Liquidated Damages Milestone
3.8	Acceptance of Phase 2		IPH Batut		176	190	
4	**Phase 3 - Training**						
4.1	Training of the system's users in PHIs and hospitals (oncology)		TBD		191	210	Yes
4.2	Final Deliverables		IPH Batut		211	213	Yes
4.3	Acceptance of Phase 3		IPH Batut		214	216	
5	**Final Acceptance**		IPH Batut			220	

6.15 Database model (generalized)

Proposed database model is indicative and should be adopted in accordance with findings during system design phase.


SYSTEM
PK ID
U1 LOOKUP
VALUE
sysdiagrams
PK diagram_id
U1 name
U1 principal_id
version
definition
HEALTH ORGANIZATION
PK SRID
PK SOURCE RECORD ID
NEXT_RECORD_DB_ID
LAST_RECORD_DB_ID
FK2 Hospital
Hospital ID
FK3 Hospital Unit
Hospital Unit ID
Laboratory No
Laboratory ID
Case No
FK1,FK4,I1 TUMOUR ID SOURCE TABLE
FK1,FK4 TRID
TUMOUR ID
FK2,FK3 ID
DICTIONARY
PK ID
DICTIONARY
CODE
DESCRIPTION
DICTIONARIES
PK,FK2 ID
FK1 Dictionary ID
Dictionary Name
Type
Code Lenght
Category Description lenght
FULL DICT CODE LENGTH
FULL DICT DESC LENGTH
NAMESEX
PK,FK1 ID
U1 NAME
SEX
PDSET
PK ID
PDS_ID
AGE_GROUP
SEX
COUNT
PDSETS
PK ID
FK1,U1 PDS_ID
PDS_NAME
FILTER
DATE
SOURCE
AGE_GROUP_STRUCTURE
DESCRIPTION
TUMOUR
PK TRID
PK,FK7 TUMOUR ID
NEXT_RECORD_DB_ID
LAST_RECORD_DB_ID
Record sequence
Record check
Date of Tumor
Diagnosis Date
Multipost Code
Multipost Sequence
Multipost Total
Incidence Date
Determination method
Localization primary
Localization primary Code
Localization secondary
Laterality
Diagnosis Pato-Cito
FK4 Behaviour
Differentiation degree
cTNM
pTNM
Betheseda stadium
IDC-O-3 stadium
ClarkBreslow stadium
Clinical stadium Primary tumor
Clinical stadium Limfoma
Cliical stadium metastasis
FK3 Surgery Date
FK5 Surgery Type
Radiotherapy Start Date
Radiotherapy Type
System Specific Therapy Start date
System Specific Therapy Type
Other treatment Start date
Other treatment
Treatment Outcome
Update Date
ICCC
OBSOLETE FLAG TUMOUR TABLE
PATIENT ID TUMOUR TABLE
FK1 PATIENT RECORD ID TUMOUR TABLE
TUMOUR UPDATED BY
TUMOUR UNDUPLICATION STATUS
FK1 Patent Record ID
PATIENT RECORD ID
ID
Hospital
Hospital Code
Patients Age
Medical doctor
Medical doctor ID
TREATMENT OUTCOME
PK ID
Patient Record ID
Tumor ID
Disease Outcome
Disease Outcome Date
Cause of Death
PATIENT
PK,FK3 Patient_Record_ID
PK,U1 Patient Record ID
NEXT_RECORD_DB_ID
LAST_RECORD_DB_ID
RegNO
PERS
Family Name
First Name
Parent Name
Birth Date
Gender
Unique Personal ID
Birth Place
Birth Place municipality
Residence Address
Residence place
FK1 Residence Municipality
Education
Occupation
Date Last Contact
Status
Obsolete Flag Patient Table
Patient Update By
Patient Update Date
Patient Record Status
Patient Check Status
FK2 ID

7 OUTPUTS AND PRODUCTS

Contractor shall deliver following products and outputs that are created as result of project activities:

	Product / output	Description	Reference
1	Cancer Register Information System software	Complete software created, used or deployed in order for Software Solution to operate (application software, software, application server, database server, auxiliary tools, libraries, etc.)	
2	Source code of Cancer Register Information System	Sorce code base for Cancer Register Information System	
3	System design document	High level description of the desired application, criteria for completion and milestones	6.4 System design
4	Software Solution documentation	Technical documentation of software solution	6.12.2 The Software Solution Technical Documentation
5	User manuals	Instructional materials for end users	6.12.1 End user documentation
6	Training materials	Materials used for training of end users	6.11 Training
7	Administrator documentation	Materials necessary for information system administration and management	6.12.3 System administration documentation
8	Quality Assurance report	Discibes results of investigation, findings and results on quality assurance reference model.	6.13 Quality Assurance
9	Test plan	Describes plan for testing of functional and non-functional requirements, system performance, and tests to be used	6.14 Testing
10	Test report	Describes findings of testing actions to check the fulfillment of functional and non-functional requirements, as well as system performance through the process of controlled testing	6.14 Testing
11	Final project report	Contains brief description (1) activities, (2) software solution description and deplyoment and (3) conclusions / findings	

	Product / output	Description	Reference
		found out during development and deploymnet of CR-IS.	

8 Requirements of the Consultants Technical Team

The consultant must fulfill the following conditions:

8.1 Economic – Financial capacity of the Consultant

1. The Consultant, over the course of the past three years has had turnover worth at least 150,000.00 EUR derived from provision of information technology products and services;

8.2 Technical competences of Potential Consultant

1. That the working processes of the Consultant are compliant with the following standards: ISO/IEC 27001, ISO 20000;
2. Over the past 3 years, the Consultant has had at least two contracts awarded in relation to the development and implementation of software solutions in the field of health of similar nature as one being purchased.

Proof thereof is to be presented by means of valid contracts defining the subject of the procurement. The Consultant will describe software solutions. Description should include short description of information system, users' base, technologies, development period, client and client's contact info. In case that Consultant did not deliver system independently (was part of a consortium), Consultant shall provide clear description of conducted activities, as well as provide names and contact info of other parties.

8.3 Capacities of the Personnel

In addition to the aforementioned conditions, the Consultant must provide a team for the implementation of the system comprising the following members:

Project Manager (1 employee):

- At least 10 years working experience in leading complex projects and project teams.
- At least 7 years' experience in the development and maintenance of information systems, out of which 5 years experience should be in the field of Information and Technology Systems in health care.
- A Scrum Master / Agile certification will be considered as an advantage.

Business System Analyst (1 employee):

- At least 5 years' experience in design and development of software systems within the health system,
- Experience in modeling and optimization of business processes,
- Experience in the shaping of business processes within such fields as public health or the health system,

Software Systems Architect (1 employee):

- At least 10 years' experience in the development of the architecture of software systems
- Experience in design within field of health care

Senior Programmer (1 employees):

- At least 8 years of experience in the development of software in the proposed technology.

Intermediate Programmer (2 employees):

- At least 5 years of experience in software development in the proposed technology.

The conditions listed for team members are to be proven by means of submitted CVs.

Appendices

ANNEX 1 – Situation Analysis Of Cancer Register In Serbia

1. Situation analysis of population based cancer registries

1.1. Cancer registries context

Cancer registries are key elements of a cancer control programme for data collection, analysis, interpretation and health policy implementation. It includes systemic collection, storage, analysis, interpretation and reporting of cancer related data. The two main types of cancer registry are Population Based Cancer Registries (PBCRs) and Hospital Based Cancer Registries (HBCRs). HBCRs maintain data on patients diagnosed with cancer and/or treated at a particular facility. The focus of the hospital-based cancer registry is on clinical care and hospital administration. Purpose of PBCR is to record/capture all the cancer cases diagnosed in a clearly defined geographical area. In comparison to the hospital-based cancer registry, the data collected by the population-based registry serves a wider range of purposes. Population-based cancer registry include cancer control programs, patient care programs, administrative programs, and cancer research programs. Data from population-based registries can be used for monitoring the distribution of late-diagnosed cases of cancer of the types for which early diagnosis is the strategy for control, esp., communities, ethnicities, age and other demographic groups.

There are two operating cancer registries in Serbia – (1) the Cancer Registry of Central Serbia (population-based) and (2) the Cancer Registry of Vojvodina (hospital-based). The Cancer Registry of Central Serbia is a population registry for the territory of Central Serbia and is sited at the Institute for Public Health of Serbia "Dr Milan Jovanović Batut" (hereinafter: Batut Institute or Institute of Public Health of Serbia) . The Cancer Registry of Vojvodina is a hospital registry for territory of Vojvodina and is seated at the Institute of Oncology of Vojvodina. The Cancer Registry of Central Serbia and the Cancer Registry of Vojvodina are members of the International Association of Cancer Registries (IACR), while the Cancer Registry of Central Serbia is member European Association of Cancer Registries (ENCR).

1.2. Legislation framework of the Cancer Register

Following laws and bylaws stipulate legislation framework make the Cancer Register operational:

1. The Law on Health Records and Statutory Records in the Field of Health Care (Serbian: Zakon o zdravstvenoj dokumentaciji i evidencijama u oblasti zdravstva, "Službeni glasnik RS", br. 123/14, 106/15, 105/17, 25/19)
2. The Rulebook on Templates and Data Content for Records, Statutory Records Reports, Registers and Electronic Health Record (Serbian: Pravilnik o obrascima i sadržaju obrazaca za vođenje zdravstvene dokumentacije, evidencija, izveštaja, registara i elektronskog medicinskog dosijea "Službeni glasnik RS", br. 109/2016, 20/2019.)

The Law stipulates that health records and registries (Article 2) are used (among other) for monitoring the patient's health; monitoring and studying the health status of the population; monitoring and

evaluating the implementation of health care plans and programs; conducting statistical and scientific research; informing the public; fulfillment of international obligations in the field of health and for the development of health care and health insurance systems. Cancer Register befalls under all these categories - persons suffering from cancer are registered and cancer is monitored; aggregated reports are produced to report towards international comparisons and to inform public.

The Law prescribes (Article 29) that health organization will create individual report on persons suffering from malign tumors and that public health institutes (Article 31) will keep registries of persons with diseases and conditions of major public health importance, on the basis of individual reports for the purpose of (among other): monitoring and studying the health status of the population; health care planning and programming; monitoring and evaluating the implementation of health care plans and programs; conducting statistical and scientific research; public information; fulfillment of international obligations in the field of health, as well as for the development of the health care system and health insurance. One of these registries is for persons suffering from malign tumor (same article, para 2 point 1).

The Institute for Public Health "Dr Milan Jovanović Batut" is obliged to keep registers of persons with diseases of major public health importance for the territory of the Republic of Serbia (Article 32).

County public health institutes are obliged to submit to the Institute of Public Health of Serbia collected and processed individual reports of persons with diseases of major public health importance for which they keep the registries. Deadline to do so is the end of the current month for the previous month. (Article 32, para 2).

Health facilities, private practice and other legal entities are obliged to submit individual report on cancer (reports, notification of change and deregistration) within ten days from the day of establishing the disease or confirmation of diagnosis (Article 34). Exception is established if health facility keeps health records and registries in electronic form - individual and summary reports shall be submitted by the 10th of the month for the previous month.

Public health institutes (county level) are obliged to submit the consolidated individual reports electronically, in electronic form to the Institute of Public Health of Serbia, by the 30th of the month for the previous month (Article 35). County public health institutes from Vojvodina shall submit the consolidated individual reports electronically in electronic form to Institute for Public Health of Vojvodina, by the 30th of the month for the previous month (Article 35).

The Institute of Public Health of Serbia consolidates data from individual and summary reports submitted by public health institutes and forms appropriate database in accordance with the law and regulations (Article 36). The Institute of Public Health of Serbia shall submit annual report to the ministry of health and other organizations, no later than September 30 of the current year for the previous year (Article 36, para 2). In addition, the Institute is obliged to make processed aggregate data available to the public (Article 36, para 3).

The Rulebook stipulates that individual reports shall be submitted on persons suffering from malign tumors (Article 15) from moment when the condition was confirmed followed by reports when changes occur. Public health institutes shall keep population-based registries (Article 19) for, among

other diseases and conditions, persons with malignant tumors using individual reports as main source of information.

The Institute of Public Health of Serbia shall collect and aggregate individual data for the territory of the Republic of Serbia (Article 20). Public health institutes are obliged to send collected and processed individual reports, changes and deregistration of persons suffering from diseases for which they keep registers, to the Institute at the latest by the end of the current month for the previous month.

The Registration form for Persons with Malignant Tumor is in Annex 2.

1.2.1. Historical legislation framework

Following legislation shaped content of population based cancer registries in Serbia:

1. Instruction on the manner and procedure for reporting persons with malignant neoplasms (Serbian: Uputstvo o načinu i postupku prijavljivanja lica obolelih od malignih neoplazmi (Sl. list SFRJ, br. 3/86)),
2. Rulebook on the Register Form and Manner of Keeping it, the Application Form and the Procedure for Reporting and Deregistration of Certain Diseases (Serbian: Pravilnik o obrascu Registra i načinu njegovog vođenja, obrascu prijave i postupku prijavljivanja i odjavljivanja određenih bolesti (Sl. glasnik SRS, br. 42/86)).
3. Law on statistic research and the Program of statistical research in health area (Serbian: Zakon o statističkim istraživanjima i Programom statističkih istraživanja u oblasti zdravstva ("Sl. list SRJ", br. 46/98));
4. Law on Health Records in Health Area (Serbian: Zakon o evidencijama u oblasti zdravstva (Sl. list SRJ 12/98));
5. Rulebook on Means for Keeping Records in Health Area (Serbian: Pravilnik o sredstvima za vođenje evidencija u oblasti zdravstva (Sl. list SRJ 6/2000);

The Rulebook on Means for Keeping Records in Health Area specified the Registration form for Persons with Malignant Tumor (Serbian: Prijava lica obolelog od malignog tumora, obr. br. DI-08/01), which holds less information that current the Registration Form.

The Registration form for Persons with Malignant Tumor (Serbian: Prijava lica obolelog od malignog tumora, obr. Br. DI-08/01) is in Annex 3.

1.3. Operational framework for the Cancer Register of Serbia

Following document describes operational framework and procedures for cancer cases collection:

1. Cancer Register - Organization and Methodology, published in 2006 (Serbian: Registar za rak – Organizacija i metodologija rada, 2006, Institut za javno zdravlje Srbije „Dr Milan Jovanović Batut“)

The Methodology defines roles and responsibilities of actors from health organizations (hospitals) and other public heath institutions and touches upon organization of the Cancer Registry. The Methodology establishes two main principles for Registry’s functioning:

- Passive collection of registrations of persons with malignant tumor; and
- Active collection of data on persons that become ill or deceased from cancer from all available information sources.

In practice, it means that initial registration of cancer cases is up to medical doctors – after a cancer is confirmed by one or more diagnostic procedures and/or methods, and follow up – what is happening with patient with cancer - is up to public health institutes staff.

However, it is important to notice that each instance when new cancer appears (either at new patient, or with patient already registered with malignant tumor) it is responsibility of medical doctor (from hospital) to report new case.

Another document that carries part of operational procedures is CanReg 4 User Manual

2. CanREG 4 User Manual, prepared in 2006 (Serbian: CanReg 4 – uputstvo za primenu, 2006, Institut za javno zdravlje Srbije - Dr Milan Jovanović "Batut", Centar za kontrolu i prevenciju nezaraznih oboljenja).

Besides descripion how CanREG 4 sofware works, the Manual reiterates usage of certain codebooks and coding practices (suggested by ENCR) and defines standard set of individual and aggregate reports. In addition, procedures for data cleaning, case joining and case manipulation are described and introduced (in order to improve data quality)

1.4. Data sources for the Cancer Registry

There are several sources of data for the Cancer Registry and few data collection reports used.

Hospitals and other health organizations that have oncology units whose primary activity is diagnostics and treatment of cancer and operate Hospital Based Cancer Registries use one and only form to report cancer cases to the Cancer Registry. Cancer is reported only when it is confirmed – using diagnostics and laboratory findings to establish diagnosis. Cancer diagnosis is a complex process that involves several health organizations, which can be grouped as follows:

1. Institute of Oncology and Radiology of Serbia, Institute of Oncology and Radiology of Vojvodina (Sremska Kamenica), oncology clinics and oncology dispensaries - the main source of information, where data is captured form from central and hospital registers. In addition to reporting cancer patients, as additional, important sources of information from these institutions are hospitalization reports, medical histories, discharge lists;
2. Inpatient health care facilities (clinical centers, clinics, institutes, health centers, general and special hospitals). Considering that inpatient healthcare facilities are the most important source of information on cancer patients, at least one person in each of them should be responsible and aware of all aspects of methods for registering cancer patients;
3. Outpatient health care institutions (outpatient clinics) - usually provide insufficient data on persons with cancer (patients do not have complete medical records, pathohistological findings ...). However, primary care physicians are often the first to encountered patients and send them to inpatient care facilities. In case of some cancer patients, the most often the elderly who refuse to be fully diagnosed (invasive diagnostic procedures), primary care physicians are the only source of information;

4. Histopathological laboratories – it is expected that these organizations submit their reports or copies of the reports directly to the Registry, but most often this is not the case. Pathohistological findings represent the most valid, but not the only, information on the diagnosis of a malignant tumor;
5. Hematology and other laboratories – as they diagnostics increased alkaline phosphatase in prostate cancer, alpha-keto protein in hepatocellular carcinoma, plasma proteins in multiple myeloma, other tumor markers, findings from these organizations should provide additional information;
6. Institutes / Departments and Forensic Services – as their role is to examine cause of death, autopsy report is useful and of great importance, especially for cases of cancer that have only been discovered at autopsy. The information obtained from this source of information is taken into account when evaluating incidence rates.

Private clinics, clinics and surgeries – so far, the Registry does not have an arrangement with private clinics and surgeries. Collaboration should be established, hopefully through a pathologist(s), because number of patients are being treated at home, and these healthcare facilities only come for occasional medical exam and health checks;

1.5. Data collection for the Cancer Register

Data collection for the Cancer Register is organized using paper forms that are filled in in hospitals and clinics and diagnostic departments (radiology and pathology). Following forms are standardized and used on regular basis:

1. Registration form for Persons with Malignant Tumor (Serbian: Prijava lica obolelog od malignog tumora);
2. Hospital discharge report (Serbian: Izveštaj o hospitalizaciji, obr. br.3-21-61/62/65-Cp);
3. Death Certificate (Serbian: Potvrda o smrti, Offical Gazette of Serbia, 25/2011, 103/2018) and Statistic form in Case of Death (Serbian: Statistički obrazac u slučaju smrti, obr. DEM-2)
4. Pathohistological report (Serbian: Patohistološki nalaz)

1.5.1.1. Registration form for Persons with Malignant Tumor

Registration Form for Persons with Malignant Tumor is the only and single reporting form for cancer that is used to report cancer cases. The form consist of:

1. reporting entity: health care institutions (type of health care institution, department / organization unit, municipality where the health care facility is located and medical history / health record number);
2. patient's personal and demographic information (surname and first name, unique identification number, date of birth, gender, place of birth, address of residence and occupation);
3. malignant tumor characteristics (multiple, primary malignant tumor, date of identification of multiple tumor, date of determination of present disease, method of determination of present disease, primary and secondary anatomical localization, histological type of malignant tumor and clinical stage of disease before primary therapy), and

4. outcome of the disease (date of death, main cause of death and information on whether the deceased person was examined (by coronary)).

The form complies with contemporary standards for cancer data set (a minimal set of required information), plus epidemiological and clinical cancer data recommended by the International Registry Associations (IARC, ENCR).

1.5.1.2. Hospital Discharge Report

Hospital Discharge Report shall be completed for each person who has been treated for any illness or condition at a hospital inpatient service. In case of transfer of patients from one clinic to another, a new patient-statistics sheet is opened. If a patient have entered hospital in this year and treatment continues in next year, current Report will be closed on 01-January and new one will be opened from 01-January.

1.5.1.3. Death Certificate and Statistic Form in Case of Death

A death certificate is issued ex officio by health institution or medical doctor in charge, or at the request of a person who is required by law to report the fact of death, according to place of death (regardless of where the deceased was permanently resident).

The death certificate is issued in triplicate. Health institution (or doctor in charge) retains one copy and two copies are forwarded to the registrar, that is, issued to the person who is legally required to report the fact of death. Two copies are sent to registrar – one copy is inserted into the register, and the second copy is joined with the Statistics Form in Case of Death (form DEM2) and sent to authority responsible for statistics.

The registration of diagnoses of the cause of death (immediate, antecedent and underlying as well as other significant conditions, diseases and injuries that contributed to the death and encryption thereof, and according to the Definitions in ICD 10) is the responsibility of the physician completing the certificate.

Institute for Statistics forwards DEM-2 form and the Death Certificate to institute for a public health in charge. Within thirty days, the institute of public health is obliged to return the DEM-2 forms and the death certificate to the statistics office with the checked and, where missing, codes of the cause of death.

1.5.1.4. Histopathological report

In addition to data that is captured using registration form, additional data is captured from the Institute of Oncology and Radiology, other health care organizations where cancer patients are diagnosed, treated and rehabilitated, as well as from other organizations that can come into possession of cancer related data such are health insurance fund, forensic services / institutes.

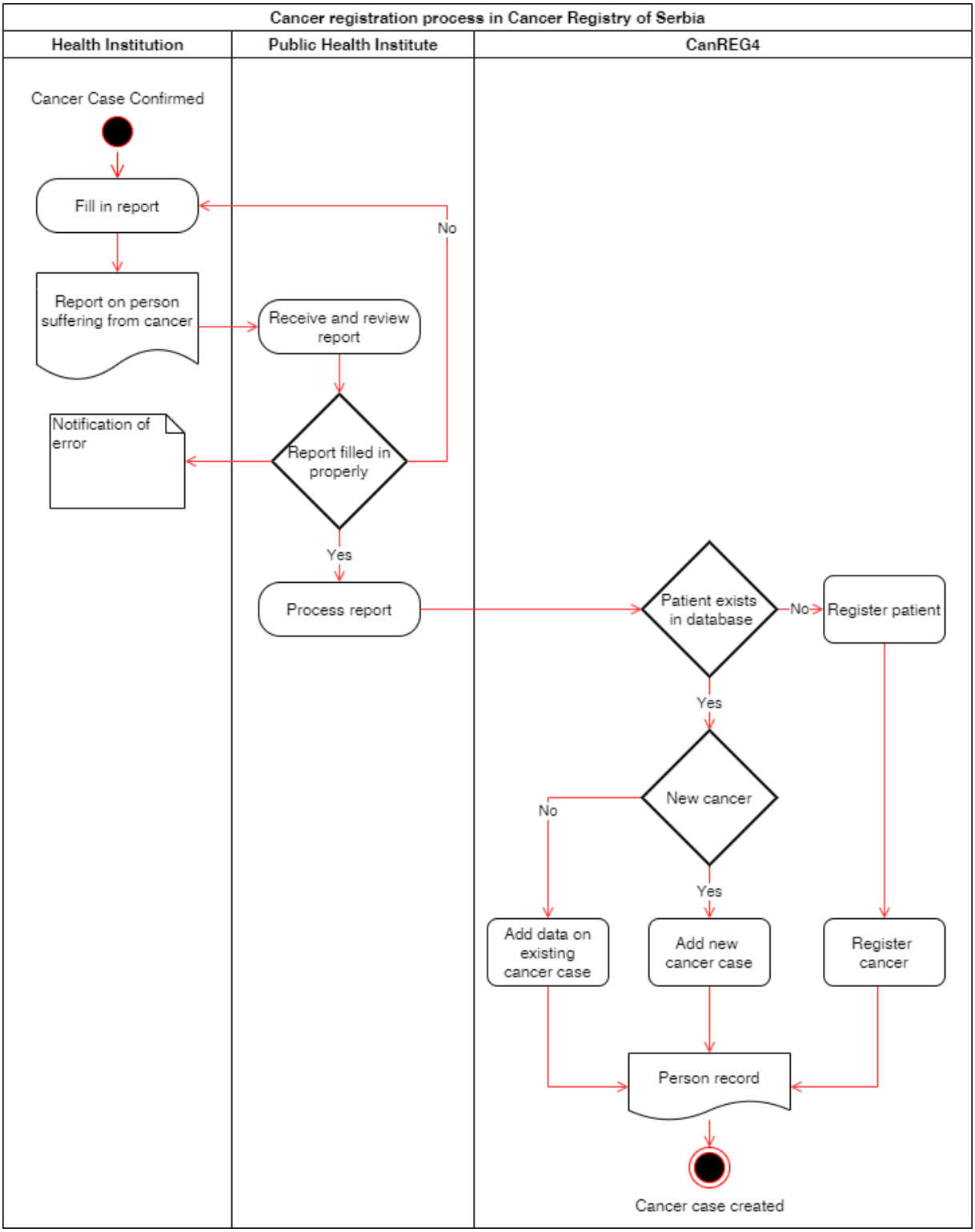
Content of histopathological report depends on type of examination requested, i.e. type of cancer on which suspicion exists. However, reported data can be generalized in following way:

- reporting entity: health care institution (type of health care institution, department / organization unit, municipality where the health care facility is located and medical history / health record number, medical doctor that requested the diagnostics, number of report, date of report);
- patient's personal and demographic information (surname and first name, unique identification number, date of birth, gender, place of birth, address of residence and occupation);
- characteristics of study (state the marker of interest, patient characteristics and inclusion and exclusion criteria, type of material used, how biomarker was assessed, clinical endpoints examined);
- findings (diagnosis, malignant potential, tumor disease stadium, residual status); and
- who conducted examination study (date of examination, name and validation of medical doctor, date of report).

1.6. Procedure for registering a person with a malignant tumor

The process for registering a person with a malignant tumor is standardized procedure as prescribed in methodological instruction for registration of cancer cases – Cancer Register: Organization and methodology of work (published by Institute for Public Health „Dr Milan Jovanović Batut", Center for control and prevention of non-communicable diseases, 2006). Medical doctors from hospitals, oncology dispensaries and oncological clinics are the most frequent, almost exclusive actors that initiate procedure for submitting a registration form for persons with malignant tumor.

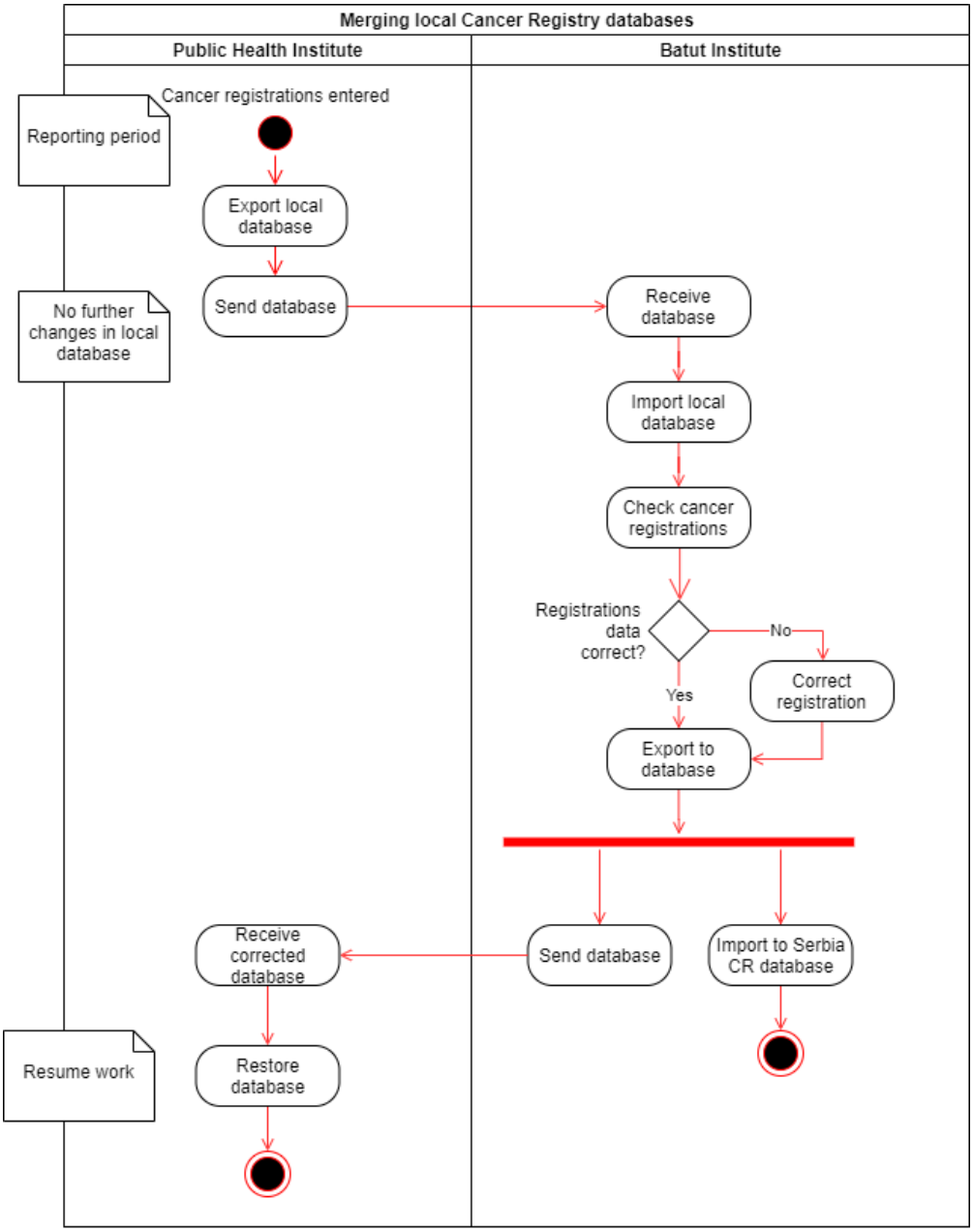
It is important to separate tasks preceding submission of an individual report on a new cancer case and tasks of patient treatment from registering a cancer case that is the interest of Cancer Register. Medical doctor, once when diagnostic procedures are finished and cancer is confirmed, fill in the report, which is sent to county institute for public health, where the reports are collected and data from the registration from manually entered into application software. Current practice is that only the registration form is submitted, however, the methodological instructions looks for evidences that can come with other information sources.



County institutes for public health follow up instructions from the methodology in order to secure expected quality level of data. If a registration does not conform (not properly filled in, there are logical mistakes), the registration is returned to health facility for missing information. If the registration holds information on patient that is registered for the first time, the whole application is entered. Otherwise, if a patient exists in database, i.e. there is a record that saying that patient suffers from a cancer, that

only new data is entered about the cancer. The record can hold information on (1) changes of existing cancer, or (2) can be record of new cancer that patient has suffered.

When the reporting period arrives, each county public health institute sends its local database of cancer registrations created in CanReg 4 to Batut Institute. Local databases are sent via email to Batutu Institute where they are checked for errors. Once checked, the confirmed, checked database is sent back to respective public health institute and a copy is merged with databases of other public health institutes to create cancer registry for Serbia. While Batut Institute is checking correctness of data, the county public health institute to whom the database belongs halt further processing of registration.



1.7. The Cancer Register of Serbia

1.7.1. Organization of the Register

The Cancer Register of Serbia is organized in line with the Law and Rulebook that legally stipulate organization of a cancer register (see section 1.2. Legislation framework of the Cancer Register).

The Cancer Registry is decentralized and operates as a cross-organizational task force, with two tiers of responsibility. First tier represents public health institutes that are in charge for counties, and second tier is the Institute for Public Health "Dr Milan Jovanović Batut". Each public health institute that operates on first tier is an entry point to the Cancer Register. Hospitals and other health institutions submit cancer reports to these organizations that are responsible for collection, control and processing of applications. Each regional public health institute runs cancer register for area of its jurisdiction, which means that there 24 county registers. However, there is some inconsistency - IPHs of Požarevac, Zaječar and Niš share jurisdiction over two counties. Regional public health institutes send reports to the second tier (level), i.e. Batut Institute in form of an Access database where all reports are consolidated in one database for Serbia. As such, Batut institute operates the Cancer Register database for Serbia.

First tier		**Second tier**
1. IZJ Vojvodine	13. ZJZ Kraljevo	IJZ "Dr Milan Jovanović Batut"
2. IZJ Niš	14. ZJZ Kruševac	
3. IZJ Kragujevac	15. ZJZ Vranje	
4. Gradski ZJZ Beograd	16. ZJZ Valjevo	
5. ZJZ Subotica	17. ZJZ Sremska Mitrovica	
6. ZJZ Sombor	18. ZJZ Šabac	
7. ZJZ Zrenjanin	19. ZJZ Užice	
8. ZJZ Kikinda	20. ZJZ Ćuprija	
9. ZJZ Požarevac	21. ZJZ Pirot	
10. ZJZ Zaječar	22. ZJZ Pančevo	
11. ZJZ Leskovac	23. ZJZ Novi Pazar	
12. ZJZ Čačak	24. ZJZ Priština-Kosovska Mitrovica	

1.7.2. Human resources

It is estimated that approximately 200 to 250 health professionals interact and participate in work and operations of the Cancer Register of Serbia. These health professionals can be grouped depending where they coming from:

1. Institutes of public health, and
2. Health care providers in charge for oncological treatment of patients.

1.7.2.1. Staff of institutes of public health

The Cancer Register operates as a cross-organizational task force headed by the Institute of Public Health "Dr Milan Jovanović Batut" with a network of institutes of public health. Cancer Register utilize staff form all public health institutes, usually form epidemiology organizational unit. These medical doctors and technicians (registrants) usually perform other tasks as well, saying that the Cancer Register in not the only responsibility. Total staff that is involved with tasks sums up to 50 persons.

	Public Health Institution	**Organizational unit**	**Medical doctors**	**Registrant (technician)**
1)	IJZ "Dr Milan Jovanović Batut"	Epidemiology	2	1
2)	IJZ Vojvodine	Biostatistcs and Informatics	2	1
3)	ZJZ Subotica	Epidemiology	1	1
4)	ZJZ Sombor	Epidemiology	1	1
5)	ZJZ Kikinda	Epidemiology	1	1
6)	ZJZ Zrenjanin	Epidemiology	1	1
7)	ZJZ Sremska Mitrovica	Epidemiology	1	1
8)	ZJZ Pančevo	Epidemiology	1	1
9)	ZJZ Šabac	Epidemiology	1	1
10)	GZJZ Beograd	Biostatistcs and Informatics	2	1
11)	ZJZ Valjevo	Social medicine	0	1
12)	ZJZ Požarevac	Epidemiology	1	1
13)	ZJZ Kragujevac	Epidemiology	1	1
14)	ZJZ Užice	Epidemiology	1	1
15)	ZJZ Čačak	Epidemiology	1	1
16)	ZJZ Ćuprija	Epidemiology	1	1
17)	ZJZ Zaječar	Epidemiology	1	1
18)	ZJZ Kraljevo	Epidemiology	1	1
19)	ZJZ Novi Pazar	Epidemiology	2	1
20)	ZJZ Kruševac	Epidemiology	1	1
21)	ZJZ Pirot	Epidemiology	1	1
22)	IJZ Niš	Epidemiology	1	1

	Public Health Institution	Organizational unit	Medical doctors	Registrant (technician)
23)	ZJZ Leskovac	Epidemiology	1	1
24)	ZJZ Vranje	Social medicine	1	1
	TOTAL		27	24

1.7.2.2. Network of oncology centers

There is a number of health organizations in Serbia that provide health services directly related to discovery and treatment of cancer. This network consists of following public health organizations:

Institutes and regional centers

1. Institute of Oncology and Radiology of Serbia (Belgrade) (182 MDs),
2. Oncology Institute of Vojvodina (Sremska Kamenica) (121 MDs)
3. Oncology Clinic of Niš (39 MDs)
4. Center for Oncology and Radiotherapy Kragujevac (13+5+6 MDs)
5. Institute of Oncology and Radiotherapy Kladovo of HC Kladovo (no data)

Oncology dispensary

Oncology dispensary employ on average one to two medical doctors.

6. Clinical Hospital Center Kragujevac
7. Hospital Novi Sad
8. General hospital Bor
9. Medical center Smederevo
10. Health center Požarevac
11. Medical Center Valjevo
12. PHC center Šabac
13. Health Center Loznica
14. Health Center Leskovac
15. Health Center Pirot
16. PHC center Vranje
17. Medical Center Zaječar
18. Health Center Zrenjanin
19. Health Center Subotica
20. Health Center Pančevo
21. General Hospital Užice
22. Health Center Čačak
23. Health Center Gornji Milanovac
24. Health Center Ćuprija
25. Health Center Paraćin
26. Health Center Studenica
27. Health Center Novi Pazar
28. Health Center Kruševac
29. Health Center Prokuplje
30. General hospital Smederevska Palanka
31. Health Center Sombor
32. Health Center Vršac

Network of oncology centers include health organizations where health professionals – medical doctors – examine patients on possibility of cancer, and this is where, in the almost all cases, a cancer case will be confirmed for the first time. In any given time, approximately 100 to 150 medical doctors are tasked with diagnosis and treatment of cancer cases. However, larger number of medical doctors

participate in treatment and care for patient – in doing so they produce documents that carries information necessary for Cancer Register.

In addition to staff of the Cancer Register numbering around 50 users (two roles) there are potentially 80 medical doctors (one role) that are submitting registration forms for persons with malignant tumor.

1.8. Data Entities and Volumes

In registries that have been operating for decades, due to the many sources of data and the need to verify and analyze them, the usual time for data collection and verification is two years, after which a report is published.

In order for Cancer Register to fulfill its mission (i.e. to track cancer cases, report on cancer incidence in various ways and give prognosis and trends) key entities are (1) "Cancer case" and (2) "Patient". Appearance of a cancer case is an event that triggers registration procedure and is one that is being monitored - information is added to map outcomes for that instance of cancer. Second key entity is a "patient" which health status is being recorded once when status of a cancer changes. "Patient" is defined as a unique entity, with restrictions defined around it. The Register takes measures to avoid duplications of cancer cases, diagnosis and health statuses – however, patient can suffer from more than one cancer, and more than one cancer case can apply to a patient. Patient can get better and cured, or can get worse and die – in both cases, cancer case (or cases if patient suffered from more than one cancer) is closed.

	Public Health Institution	Number of new cancer cases	Number of death cases (data from RSO*)	Number of pato-histology confirmed cases	Number of only DCO cases
1)	*IJZ "Dr Milan Jovanović Batut"*	*40.241*	*21.526*	*34.563*	*1.966*
2)	IJZ Vojvodine	3.233	1.910	2716	194
3)	ZJZ Subotica	1.294	609	1113	65
4)	ZJZ Sombor	1.250	647	1075	63
5)	ZJZ Kikinda	968	534	832	39
6)	ZJZ Zrenjanin	1.241	576	1067	48
7)	ZJZ Sremska Mitrovica	2.062	1.026	1773	48
8)	ZJZ Pančevo	1.553	938	1336	48
9)	ZJZ Šabac	1.428	835	1228	71
10)	GZJZ Beograd	9.385	5.351	7977	375
11)	ZJZ Valjevo	947	498	814	47

	Public Health Institution	Number of new cancer cases	Number of death cases (data from RSO*)	Number of pato-histology confirmed cases	Number of only DCO cases
12)	ZJZ Požarevac	1.694	1.088	1457	152
13)	ZJZ Kragujevac	1.860	771	1600	93
14)	ZJZ Užice	1.317	757	1133	66
15)	ZJZ Čačak	1.156	596	994	58
16)	ZJZ Ćuprija	1.074	626	924	104
17)	ZJZ Zaječar	1.368	766	1176	56
18)	ZJZ Kraljevo	1.533	609	1318	58
19)	ZJZ Novi Pazar	410	121	359	29
20)	ZJZ Kruševac	1.533	730	1318	77
21)	ZJZ Pirot	555	232	477	33
22)	IJZ Niš	2.629	1.339	2208	131
23)	ZJZ Leskovac	1.120	579	963	56
24)	ZJZ Vranje	817	386	703	54
	TOTAL	40.241	21.526	17.281	1.966

1.8.1. Software support for Cancer Register

CanReg4 is an application released in 2001 with modules for data entry (patients with cancer), analysis (some options for basic summary, analysis, calculating cancer incidence rates), and management (view work files, back up database, and check/search for quality assurance – duplicate search and name / sex check). It has rudimentary quality control and consistency checks. Database(s) are stored in files on local disc.

CanReg4 is provided by the International Agency for Research on Cancer (IARC) to members of the International Association of Cancer Registries (IACR). CanReg4 used at the Institute of Public Health of Serbia since 2001, has adopted international standards and nomenclatures that allow for international comparisons and collaboration between different cancer registries.

The data entered into the software is also aligned with national needs, with the nomenclature and definitions of each entity consistent.

Each county public health institute has one CanReg 4 installation.

CanReg 4 has command to make a copy of database. The Manual instructs public health institutes to send copy of database (via email or on a transferable media) to the Institute of Public Health of Serbia.

No changes to the databases are allowed until the database is returned with checked and updated data. Work in county public institute can be continued only after one receive the database from the Batut Institute, and when the database (checked and updated) is restored locally.

All changes made to local database of county public health institute in period between sending a copy of local database and receiving it back are lost – current copy of database is effectively overwritten.

1.8.2. Hardware used for Cancer Register

Institutes of public health oraganizational units that operate as part of Cancer Register as a cross-organizational task force, use older generations PC (5+ years old) to run CanReg 4.

1.9. Hospital based cancer registers

1.9.1. Oncology and Radiology Institute of Serbia

Hospital based Cancer Registry of Oncology and Radiology Institute of Serbia operates as a part of hospital information system, that is operated by the Data Center Department. The Department was founded in November 1994 with the idea to provide IT, statistical and technical support to the scientific and research work of the Institute of Oncology and Radiology of Serbia. Data Center is significant support to the daily health care activities of the Institute and to the scientific research.

Department develop dedicated applications:

HEM - monitoring program for patients with locally initiated clinical trials;

APO - pharmacy program,

ANT - antibiogram program,

Department operates and administers HELIANT Hospital Information System with modules for Scheduling, Electronic Health Record, Hospital Treatment, Outpatient Examination Consultation.

Local network connects over 350 computers.

Data Center offers accredited education course for health professionals that completed more than 120 empyloees of the Institute.

1.9.2. Oncology Institute of Vojvodina

Hospital based Cancer Registry of Vojvodina is situated in the Oncology Institute of Vojvodina, and run by Department of Epidemiology. The Registry provides methodological support at the field of malignant diseases registration for oncologic dispensaries, institutes of public health, and other medical institutions at the territory of Vojvodina. The Registry holds data for territory of 44 municipalities of Vojvodina. The Registry is a member of International Association of Cancer Registries.

Software REGMAN, for management of the cancer registry was developed by the Computer Center of the Institute. This software has been in implementation since June 1991 and the updated version REGMAN 2.0 since February 1996. The database contains data since 1981.

Software can produce reports:

- CHARACTERISTICS - the most significant epidemiological characteristics in Vojvodina
- TRENDS - trends of the 5 most frequent cancer localizations in Vojvodina with the projection, and with annual crude incidence and mortality rate
- COLOR ATLAS - color atlas of incidence and mortality for 44 municipalities in Vojvodina, grouped in 7 classes

ANNEX 2 - Registration form for Persons with Malignant Tumor (current)

PRIJAVA LICA OBOLELOG OD MALIGNOG TUMORA

Zdravstvena ustanova	1 Naziv zdravstvene ustanove
	2 Naziv zdravstvene ustanove (šifra)
	3 Služba/odeljenje
	4 Služba/odeljenje (šifra)
	5 Broj istorije bolesti – kartona
Demografski podaci	6 Prezime, ime roditelja/staratelja, ime
	7 Datum rođenja
	8 JMBG
	9 Uzrast
	10 Pol
	11 Mesto rođenja
	12 Opština rođenja (šifra)
	13 Prebivalište (ulica i broj, mesto)
	14 Opština prebivališta (šifra)
	15 Najviši stepen obrazovanja
	16 Zanimanje (šifra)
Dijagnoza prethodnog tumora	17 Drugi primarni maligni tumor koji je prethodio sadašnjem
	18 Multiplost tumora
	19 Naziv zdravstvene ustanove u kojoj je postavljena dijagnoza drugog primarnog malignog tumora
	20 Naziv zdravstvene ustanove (šifra) u kojoj je postavljena dijagnoza drugog primarnog malignog tumora
	21 Godina utvrđivanja prethodnog malignog tumora
Dijagnoza sadašnjeg tumora	22 Datum postavljanja dijagnoze sadašnjeg tumora
	23 Način utvrđivanja sadašnjeg tumora
	24 Primarna lokalizacija tumora
	25 Primarna lokalizacija tumora (šifra)

	26 Sekundarna lokalizacija tumora
	27 Lateralnost
	28 Patohistološka/citološka dijagnoza tumora
	29 Ponašanje tumora
	30 Gradus/stepen diferencijacije tumora
	31 Stadijum solidnih tumora – cTNM
	32 Stadijum solidnih tumora – pTNM
	33 Stadijum (Bethesda, ginekološki tumori)
	34 Stadijum (ICD-O-3, limfomi)
	35 Stadijum (Clark/Breslow, melanom)
	37 Klinički stadijum solidnih tumora – primarni tumor
	38 Klinički stadijum solidnih tumora – limfne žlezde
	39 Klinički stadijum solidnih tumora – metastaze
<u>Lečenje</u>	40 Hirurgija – datum operacije
	41 Vrsta operacije (šifra)
	42 Radipoterapija – datum početka zračenja
	43 Vrsta radioterapije
	44 Sistemska specifična terapija – datum početka terapije
	45 Vrsta sistemske specifične terapije
	46 Drugi način lečenja -datum početka
	47 Vrsta drugog načina lečenja
	48 Lečenje je bilo
<u>Ishod bolesti</u>	49 Ishod bolesti
	50 Datum ishoda bolesti
	51 Šifra osnovnog uzroka smrti (MKB)
	<u>Administracija</u>
	52 Datum prijave
	53 Potpis i faksimil lekara
	54 Broj faksimila

ANNEX 3 - Registration form for Persons with Malignant Tumor (in force 2000 – 2015)

(Serbian: Prijava lica obolelog od malignog tumora);

Обр. бр. ДИ-08/1

Здравствена установа/установа:	МАТИЧНИ БРОЈ
Служба – одељење:	ШИФРА
Место, општина:	ШИФРА ОПШТИНЕ
Број историје болести-картона:	БРОЈ ИСТОРИЈЕ БОЛЕСТИ-КАРТОНА

ПРИЈАВА ЛИЦА ОБОЛЕЛОГ ОД МАЛИГНОГ ТУМОРА

1. Презиме, (име једног од родитеља) и име:		
2. Јединствени матични број грађана (ЈМБГ):	ЈМБГ	
3. Датум рођења (дан, месец, година):		ДАН, МЕСЕЦ, ГОДИНА
4. Пол:	Мушки – 1 Женски – 2	
5. Место рођења:	Место, општина	ШИФРА НАСЕЉА
6. Место сталног боравка:	Улица и број, место, општина	ШИФРА НАСЕЉА
7. Занимање-посао који обавља:		
8. Да ли је раније утврђен неки други примарни малигни тумор:	Да – 1 Не – 2	
Датум утврђивања претходног малигног тумора:		ДАН, МЕСЕЦ, ГОДИНА
9. Датум утврђивања садашњег обољења:		ДАН, МЕСЕЦ, ГОДИНА
10. Начин утврђивања садашњег обољења:	- потврда о смрти....0 - клинички (само преглед)....1 - специјалном клиничком претрагом....2 - експлоративном операцијом....3 - биохемијским-имунолошким тестом..4 - цитолошки / хематолошки....5 - хистолошки (метастаза)....6 - хистолошки (примарна)....7 - обдукцијом (хистолошки)....8 - непознато....9	
11. Примарна анатомска локализација малигног тумора	Дијагноза:	ШИФРА МКБ-10
12. Секундарна анатомска локализација малигног тумора	Дијагноза:	ШИФРА МКБ-10
13. Хистолошки тип малигног тумора	Дијагноза:	ШИФРА ICD-O3
14. Клинички стадијум обољења пре примарне терапије:	- in situ....0 - локализован на органима и ткивима извора....1 - проширеност на суседне анатомске структуре 2 - захваћене регионалне лимфне жлезде....4 - удаљене метастазе....5 - непознат....9	
15. Датум смрти		ДАН, МЕСЕЦ, ГОДИНА
16. Основни узрок смрти	Дијагноза:	ШИФРА МКБ-10
17. Обдукован	Да – 1 Не – 2 Непознато – 9	
18. Датум пријаве (дан, месец, година)		ДАН, МЕСЕЦ, ГОДИНА

(презиме и име лекара) (потпис и факсимил лекара)

Обр. бр. 3-21-61/62/65-Ср

ИЗВЕШТАЈ О ХОСПИТАЛИЗАЦИЈИ

1	НАЗИВ ЗДРАВСТВЕНЕ УСТАНОВЕ				
2	ОДЕЉЕЊЕ НА ПРИЈЕМУ				
3	БРОЈ ИСТОРИЈЕ БОЛЕСТИ		4	ДАТУМ ПРИЈЕМА	
5	ИМЕ И ПРЕЗИМЕ ПАЦИЈЕНТА				
6	ЈМБГ		7	ДАТУМ РОЂЕЊА	
8	ДРЖАВЉАНСТВО		9	ПОЛ	1 – М 2 – Ж
10	АДРЕСА И ОПШТИНА ПРЕБИВАЛИШТА				
11	ОСИГУРАЊЕ	1 – ДА 2 – НЕ	12	ЛБО	
13	УПУТНА ДИЈАГНОЗА				
14	ПОВРЕДА	1 – ДА 2 – НЕ	15	СПОЉНИ УЗРОК ПОВРЕДЕ ПО МКБ	
16	ОСНОВНИ УЗРОК ХОСПИТАЛИЗАЦИЈЕ				

17	ПРАТЕЋЕ ДИЈАГНОЗЕ ПО МКБ			

18	ШИФРА ПРОЦЕДУРЕ ПО НОМЕНКЛАТУРИ			

19	ТЕЖИНА НА ПРИЈЕМУ (ЗА НОВОРОЂЕНЧЕ)	(у грамима)	20	БРОЈ САТИ ВЕНТИЛАТОРНЕ ПОДРШКЕ	
21	ДАТУМ ОТПУСТА		22	БРОЈ ДАНА ХОСПИТАЛИЗАЦИЈЕ	
23	ОДЕЉЕЊЕ СА КОГА ЈЕ ИЗВРШЕН ОТПУСТ				

24 ВРСТА ОТПУСТА

1 – ОТПУСТ КУЋИ/ДРУГО МЕСТО ПРЕБИВАЛИШТА

2 – ОТПУСТ/ПРЕМЕШТАЈ У ДРУГУ ЗДРАВСТВЕНУ УСТАНОВУ ЗА КРАТКОТРАЈНУ ХОСПИТАЛИЗАЦИЈУ

3 – ОТПУСТ/ПРЕМЕШТАЈ У ДРУГУ ЗДРАВСТВЕНУ УСТАНОВУ

4 – СТАТИСТИЧКИ ОТПУСТ

5 – ОТПУШТЕН НА СОПСТВЕНИ ЗАХТЕВ

6 – УМРО

ОБДУКОВАН 1 – ДА 2 – НЕ

25	ОСНОВНИ УЗРОК СМРТИ	

НАПОМЕНА: ПОДАЦИ СА ОВОГ ОБРАСЦА КОРИСТЕ СЕ И ЗА ПОТРЕБЕ ЕЛЕКТРОНСКЕ ФАКТУРЕ

ПОТПИС И ФАКСИМИЛ ЛЕКАРА СПЕЦИЈАЛИСТЕ КОЈИ ЈЕ ЗАКЉУЧИО ЕПИЗОДУ БОЛНИЧКОГ ЛЕЧЕЊА

ANNEX 5 - Death Certificate

(Serbian: Potvrda o smrti, Offical Gazette of Serbia, 25/2011, 103/2018)

_____ Broj protokola: _____

(naziv zdravstvene ustanove)

_____

(sedište zdravstvene ustanove - grad/opština, ulica i broj)

|_|_|_|_|_|_|_|_|_| |_|_|_|_|_|_|

(matični broj zdravstvene ustanove) (jedinica u sastavu)

POTVRDA O SMRTI

1.	**Ime i prezime umrlog**	_____	
	Prezime pre zaključenja braka	_____	
	Ime i prezime oca	_____	
	Ime i prezime majke	_____	
2.	**Pol umrlog**	Muško	1
		Žensko	2

3.	**Datum, čas i mesto smrti / nalaženja leša** **Utvrđen (za smrt u zdravstvenoj ustanovi) ..... 1** **Prema dobijenim podacima ..... 2** **Leš je nađen ..... 3** **3.1. Mesto nastupanja smrti ..... 1** **3.2. Mesto pronalaženja leša 2**	|_|_| |_|_| |_|_|_|_| |_|_| |_|_| (dan) (mesec) (godina) (čas) (minut) Ulica i broj _____ Naseljeno mesto _____ Opština/grad _____
4.	**Datum i mesto rođenja i JMBG umrlog** |_|_| |_|_| |_|_|_|_| **Dan, mesec i godina rođenja** (dan) (mesec) (godina) **Mesto rođenja (mesto i opština/grad rođenja, a ako je umrli rođen u inostranstvu i naziv države rođenja)** _____ **JMBG** |_|_|_|_|_|_|_|_|_|_|_|_|_|	
5.	**Prebivalište umrlog**	Ulica i broj _____ Naseljeno mesto _____ Opština/grad _____ Naziv države _____
6.	**Bračno stanje umrlog** Neoženjen - neudata ..... 1 Udovac - udovica ..... 3 Oženjen - udata ..... 2 Razveden - razvedena ..... 4 **6.1. Ime i prezime bračnog druga i prezime pre zaključenja braka** _____	
7.	**Državljanstvo**	
8.	**Nacionalna pripadnost[1)]**	
9.	**Veroispovest[2)]**	

10.	**Najviša završena škola**	**11.**	**Aktivnost**
	Bez škole 1		Obavljao zanimanje u radnom odnosu 1
	Nepotpuna osnovna škola 2		Ostali koji su obavljali zanimanje 2

Osnovna škola ..... 3 _____

Srednja škola 4
Viša škola 5
Visoka škola 6

(za odgovore 1 i 2 kod aktivnosti, upisati naziv zanimanja)

Nezaposlen 3
Penzioner 4
Lice s drugim ličnim prihodom..... 5
Domaćica..... 6
Dete, učenik ili student 7
Ostala izdržavana lica 8
Lice koje je bilo na privremenom radu-boravku u inostranstvu 9

12 PODACI O UMRLOM ODOJČETU (pitanja 1-3 se popunjavaju samo za odojčad do 30 dana starosti)

1. Telesna masa na rođenju |_|_|_|_|
(u gramima)

2. Telesna dužina na rođenju |_|_|
(u centimetrima)

3. Gestaciona starost |_|_|
(navršene nedelje gestacije)

4. Datum rođenja majke umrlog odojčeta |_|_| |_|_| |_|_|_|_|
(dan) (mesec) (godina)

5. Najviša završena škola majke umrlog odojčeta

Bez škole 1
Nepotpuna osnovna škola 2
Osnovna škola 3
Srednja škola 4
Viša škola 5
Visoka škola 6

6. Aktivnost majke umrlog odojčeta

Obavlja zanimanja u radnom odnosu 1
Ostali koji obavljaju zanimanje 2
_____
(za odgovore 1 i 2 kod aktivnosti, upisati naziv zanimanja)

Nezaposlena 3
Penzioner 4
Lice s drugim ličnim prihodom 5
Domaćica 6

Učenik ili student 7
Ostala izdržavana lica 8
Lice na privremenom radu-boravku u inostranstvu 9

1. Za umrle van zdravstvene ustanove:

a) Naziv poslednje zdravstvene ustanove u kojoj je lečen _____

b) Ime i prezime poslednjeg ordinirajućeg lekara _____

2. Poreklo smrti

Prirodna ..... 1 Nasilna 2

a) Nezarazna .....1.11.1.

b) Zarazna ..... 1.21.2. Neutvrđeno 3

3. Da li je tražena obdukcija

Ne ..... 1 Da - klinička 2

Da - sudsko-medicinska 3

Da - leš je oslobođen obdukcije 4

_____

(naziv suda i broj predmeta)

PODACI O NASILNOJ SMRTI

1. Poreklo nasilne smrti:

Nesrećni slučaj - zades 1
Samoubistvo 2
Ubistvo 3
Ostalo 4

2. Vreme događaja (prema anamnestičkim podacima) koji je izazvao nasilnu smrt

|_|_| |_|_| |_|_|_|_| |_|_| |_|_|
(dan) (mesec) (godina) (čas) (minut)

Dan u nedelji _____ (ponedeljak, utorak, itd.)

3. Mesto događaja

Kuća, stan, kolektivni stan 1
Škola, druga javna mesta i institucije 2
Sportski objekti 3
Saobraćajnice 4
Fabrika, rudnik, gradilište i sl. 5
..... 6
Polje, planina, reka, jezero, more i sl. 7

4. U trenutku događaja umrli je bio

Na poslu 1
Pri odlasku ili povratku s posla 2
Na radu u domaćinstvu 3
U toku sportske aktivnosti 4
Kod kuće - u slobodno vreme 5
Poljoprivredna gazdinstva
Van kuće - u slobodno vreme 6

1. UZROK SMRTI

I

a) Neposredni uzrok _____ |_|_|_|_|

b) Prethodni uzrok _____ |_|_|_|_|
(bolest ili povreda)

v) Osnovni uzrok _____ |_|_|_|_|
(bolest ili spoljašnje okolnosti povređivanja)

_____

II

Druga značajna stanja, bolesti i povrede _____ |_|_|_|_|

	koje su doprinele smrti _____	|_|_|_|_|

2. Da li je umrli bio lečen od bolesti, povrede od koje je umro

Da ..... 1 Ne ..... 2 Neutvrđeno 3

3. Ko je dao podatke o uzroku smrti	**4.**	**Podaci o uzroku smrti su dati iz:** _____
Ordinirajući lekar 1		a) Zdravstvenog kartona br. _____
Mrtvozornik (s medicinskom dokumentacijom) 2		b) Istorije bolesti br. _____
Mrtvozornik (bez medicinske dokumentacije) 3		v) Obdukcionog nalaza br. _____
Mrtvozornik (bez medicinske dokumentacije) 4		
Obducent		g) Ostale dokumentacije br. _____
NAPOMENA:		

Na osnovu izvršenog detaljnog pregleda neobučenog leša _____ potvrđujem smrtni ishod.

(datum, čas, minut)

U _____	(M.P)	Potpis i faksimil lekara
_____ 20__.		_____

BELEŠKA MATIČARA:

Upis činjenice smrti izvršen u matičnu knjigu umrlih koja se vodi za opštinu/grad _____, matično područje _____, pod tekućim brojem _____ za _____ godinu.

MATIČAR

_____ (puno ime i prezime)

(M.P.) _____

Potpis matičara

_____

[1)] *Saglasno članu 47. Ustava Republike Srbije ("Službeni glasnik RS", broj 98/06) izražavanje nacionalne pripadnosti je slobodno i niko nije dužan da se izjašnjava o svojoj nacionalnoj pripadnosti.*

[2)] *Saglasno članu 43. stav 2. Ustava Republike Srbije niko nije dužan da se izjašnjava o svojim verskim i drugim uverenjima.*

ANNEX 6 - Statistic form in Case of Death

(Serbian: Statistički obrazac u slučaju smrti, obr. DEM-2)

ANNEX 7 - Pathohistological report

(Serbian: Patohistološki nalaz)

ANNEX 8 – Public Health (E)Service Of Institute Of Public Health Of Serbia

1. Public Health (e)Service of Institute of Public Health of Serbia

Institute of Public Health of Serbia deployed central integration component for future integrated public health information system. The central component is operational as of November 2019.

The Central integration component provides:

1. Service based data storage / cloud storage
2. Authentication and authorization service for users
3. Third party authorization
4. Logging activities

1.1. Service based data storage / cloud storage

The service based data storage is modular and easily extensible to support various data sets that can be recognized and created immediately. Data sets can be rapidly defined and deployed. Applications and third party services communicate with the central integration component using standardized data exchange format. The following is a pseudo code view of a standardized data exchange format:

1. BEGINNING OF THE MESSAGE

2. AUTHORIZATION

3. CONTENT OF THE MESSAGE

4. MESSAGE RECEIPT STATUS

5. END OF MESSAGE

The protocol for communication between actors in the system is protected (encrypted communication channel between all actors).

1.2. Authentication and authorization service for users

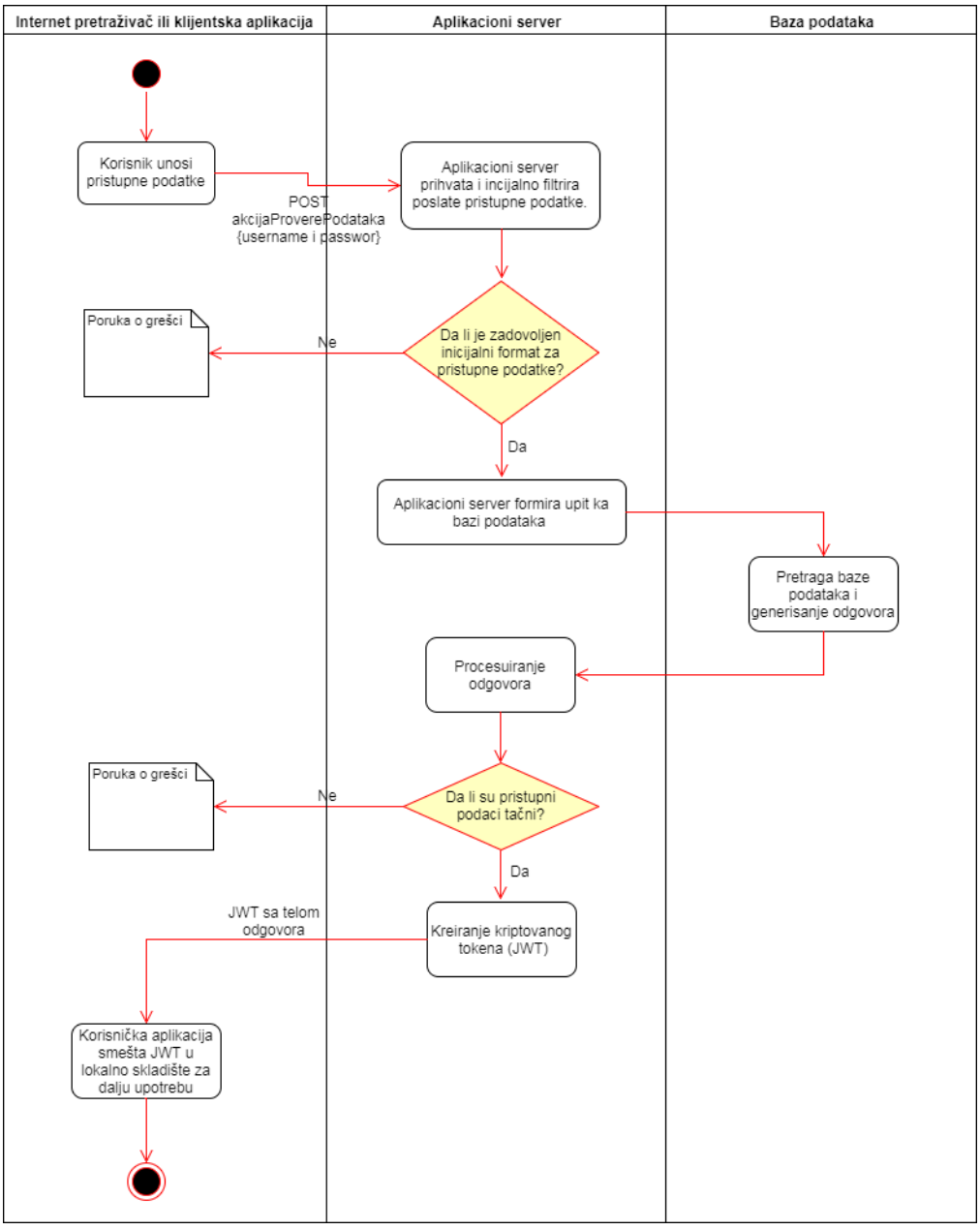
The central component has implemented a privilege / role based access control mechanism. Each role in the system should have a clearly defined protocol that defines how data is generated, distributed, and accessed.

The system uses two algorithms to perform system operations:

1. Authorization,
2. Submit authorized requests for system operations.

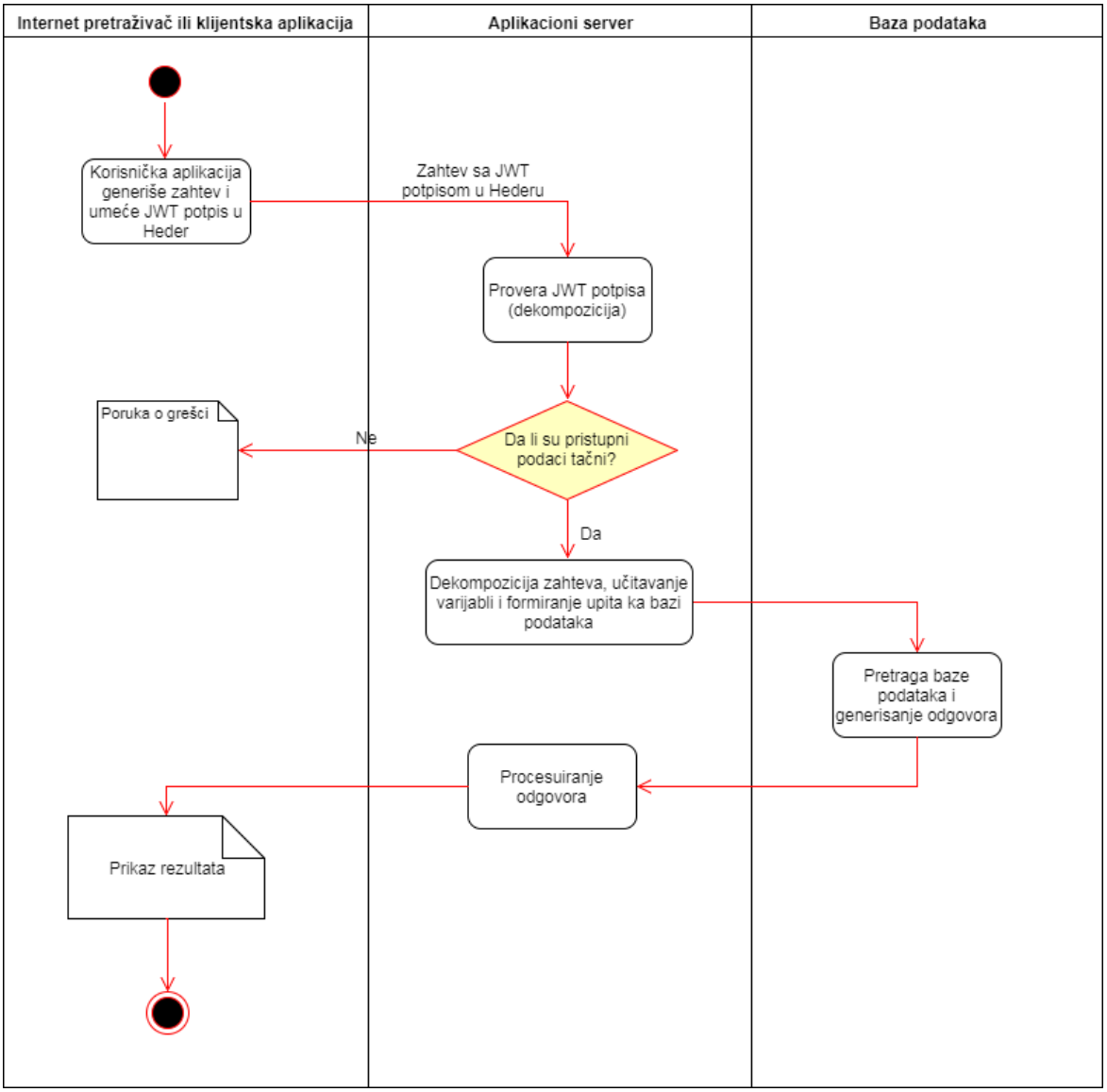
1.2.1. Authorization

The process diagram shows the workflow of generating authorization data.



1.2.2. Submit authorized requests for system operations

The process diagram shows the workflow of requesting system operations that require a user to be authorized.



1.3. Logging of all activities

Each activity on the system is recorded and registered as a log message in a separate part of the system, and sent directly to the central log system (third party log repository). This part of the system has search capabilities for authorized users with special access rights, but not the ability to modify or delete them.

Abstract log message format should include the following information:

- Activity date;
- Activity time;
- User authorization information;

- Institution to which the beneficiary is affiliated;
- IP address from which the activity was initiated;
- Part of the system affected by the registered activity (identified data set);
- A set of data that was prior to the initiation of the activity (all data readable and without references to be analyzed subsequently);
- The data set that remained after the initiation of the activity (all data readable and without references to be analyzed subsequently);
- Type of activity (allowed, illicit, suspicious);
- Log type (system-defined log types).

1.4. Message format for electronic data exchange

The message format for all services is JSON and the mandatory method of sending parameters is POST. Each request, except the one to retrieve the token, requires authorization in the header.

The format of the header is as follows:

Content-Type: application / json

Authorization: JWT

The message format is a JSON format record:

```
{
    "key1": "value1",
    "key2": "value2",
}
```

1.5. Retrieving tokens

In order to retrieve the token, which (currently) lasts for 24 hours, it is necessary to send a request to the auth service:

https://appauthorization.sjzrs.live/auth/get-token

Header

Content-Type: application / json

Body

{"username": "user", "password": "user"}

1.6. Token decomposition

In order to see the content of the token that is obtained, it is possible to call the action, which requires authorization, on the auth service:

https://appauthorization.sjzrs.live/user/check-token

Header

Content-Type: application / json

Authorization: JWT

Body

{"token": JWTWhat's NeededCheckAnYou MUST Be LikeHeader}

1.7. Data entity definition

In order to see a description of the attributes that participate in the data model, an entity definition action is called:

https://app[servicename].sjzrs.live/[servicename]/entity-definition

Header

Content-Type: application / json

Authorization: JWT

Body

{}

1.8. Description of entity field

Each entity is represented via a master node called "data". It contains 3 units that are described by nodes:

1. "keys" - presents a list and a detailed description of all fields that can be used in a data set

Each field can be described with the following options:

"key": "FIELD", // FIELD represents the attribute name in the data set

"label": "NAME", // NAME represents the label of the field, ie. its name in the data set

"type": "TIP", // TIP can be:

- text - Text free field

- dropdown_single_select - Standard select field

- date - The date field (most commonly used to create calendars on a form)

"input_limit": "VALUE", // TYPE can be:

- none - Means no predefined value is offered. Most commonly used for TIP text box (text)

- min and max - Describes the allowed date set (most commonly used to populate the default values in a calendar on a form)

- Key: Value,… Key Value - Describes a set of values used in select fields

"sort": BOOLEAN, // BOOLEAN can be

- true - Sorting by this field is allowed

- false - Sorting by this field is not allowed

"sort_type": "VALUE", // VALUE is always ASC | DESC and says sort by these options is possible

"default_value": "VALUE", //

- '' - Empty string, ie. has no default value

- Y-m-d - May have a date represented by Year-Month-Day records (standard record)

"default_output_fields": BOOLEAN, // BOOLEAN can be

- true - This field is included in the default search results

- false - This field is not included in the default search results

"default_sort_field": BOOLEAN, // BOOLEAN can be

- true - Default sorting by this field is on

- false - Default sorting by this field is not included

"default_sort_field_type": "VALUE", //

- ASC - Included in the default sort direction with ASC value

- DESC - Included in the default sort direction with DESC value

"c-visible": BOOLEAN, // BOOLEAN may be

- true - Displays on the create form

- false - Does not appear on the create form

"u-visible": BOOLEAN, // BOOLEAN may be

- true - Appears on the edit form

- false - Does not appear on the edit form

"u-readonly": BOOLEAN, // BOOLEAN can be

- true - A ban on editing this information is included. It is only possible to read this field on the edit form (most often used in combination with u-visible and then presented as a hidden field on the form)

- false - No ban on editing this information is included

"quick-search": BOOLEAN, // BOOLEAN can be

- true - Appears on the default search form (also included in the advanced search form, which is a list of all form fields)

- false - Does not appear on the default search form but is included on the advanced search form, which is a list of all fields on the form

"style": {"class": [VALUE 1, VALUE2]} // Value adds the class name to the field. Most commonly used for field width. Possible values are:

- Col-md-1 or col-md-2 or col-md-3 or col-md-4 or col-md-6 or col-md-12

2. "output" - presents a list and a detailed description of the types and possible templates to use:

"type": [{"name": "VALUE", "label": "NAME"}] // The print result type can be obtained in many ways. This record is repeatable and the following VALUE options are available:

- json - The default JSON print

- pdf - Standard PDF format

- doc - Standard Microsoft Word format

- xls - Standard Microsoft Exel format

- csv - Standard CSV format

"templates": [["name": "VALUE", "label": "NAME"]], // This node offers all possible predefined templates that belong to this data set (if any). VALUE is always its ID while the name is a brief description of the temple.

3. "operations" - is a list and detailed description of operations that can be performed on a data set, most commonly used in visual representation (frontend part). Possible options are represented by nodes in a series that can contain the following values:

- create (enable option is a boolean option that can contain 2 values: true or false, depending on whether or not it is enabled; url representing the link to the form for the said option)

- update (enable option is a boolean option that may contain 2 values: true or false, depending on whether or not it is enabled; url representing a link to the form for the said option)

- delete (enable option is a boolean option that can contain 2 values: true or false, depending on whether or not it is enabled; url representing a link to the form for the said option)

- view (enable option is a boolean option that can contain 2 values: true or false, depending on whether or not it is enabled; url representing a link to the form for the said option)

- row_click (enable option is a boolean option that can contain 2 values: true or false depending on whether or not it is enabled)

1.9. CRUD

All actions with the service based data storage are realized through actions of the service

R

To view a single record in the registry, the view action is called.

https://app[servicename].sjzrs.live/[servicename]/v

Header

Content-Type: application / json

Authorization: JWT

Body

{"regdijab_id": "1"}

C

To create a new row in the data model, the create action is called.

https://app[servicename].sjzrs.live/[servicename]/c

Header

Content-Type: application / json

Authorization: JWT

Body

{"key": "value"}

Key names can be viewed by viewing the first entry in the V action.

U

To modify an existing record an update action is called. The mandatory field to send is the primary key, in this case it is regdijab_id, and one or more fields are sent with it. Those fields that are sent enter the validation and enrollment process.

https://app[servicename].sjzrs.live/[servicename]/u

Header

Content-Type: application / json

Authorization: JWT

Body

{

"data":

{

"primary_key": "value",

…

"key": "value"

}

}

D

To delete an existing record, the delete action is called. Required and the only field to send is the primary key (id), in this case it is the value of the regdijab_d field.

https://app[servicename].sjzrs.live/[servicename]/d

Header

Content-Type: application / json

Authorization: JWT

Body

{

"query":

[{

"id": "value"

}]

}

Search

To search for existing records, the export action is called.

https://app[servicename].sjzrs.live/[servicename]/e

Header

Content-Type: application / json

Authorization: JWT

Body

{

distinct: ""

limit: 10

offset: 0

output_fields: ["regdijab_id", "regdijab_facsimile", "regdijab_date_view", "regdijab_patient_ime"]

query: {regdijab_id: "1"}

sort: [{field: "regdijab_id", type: "ASC"}, {field: "regdijab_date_view", type: "ASC"}, {field: "regdijab_date_date", type: "ASC"}]

}

A guide to search action:

- distinct - one field can be specified,

- limit - any integer number can be specified,

- offset - any integer number can be specified,

- output_fields - at least one field must be specified, and multiple fields that exist as model attributes may be specified

- query - no attributes need to be specified as search criteria, and there may be more than one. Each given field has a scope in search (the range is sent as a nested node in the json definition, so an example is for the regdijab_date_view {from: "YYYY-MM-DD", this: "YYYY-MM-DD")

- sort - no one must be specified, but if one or more is specified, the sorting type for that field must be specified. Sorting is applied in the order of definition.

ANNEX 9 – Classifications and Codebooks

Cancer Registry Information System shall utilize following code books and services which are necessary for proper functioning:

1. Register of Health Institutions of Serbia.
   Provided through Public Health (e)Service, by Institute of Public Health of Serbia). Include codes and register of internal organizational units (departments and services).
2. Register of districts, cities and municipalities of Serbia
   Provided through Public Health (e)Service, by Institute of Public Health of Serbia).
   Consists of:
   i. Codebook of municipalities in Republic of Serbia (Serbian: Šifrarnik opština u Republici Srbiji)
   ii. Codebook of settlements in Republic of Serbia (Serbian: Šifrarnik naselja u Republici Srbiji)

   as stipulated by the Decision on Unique codex of codes for data entry and coding in records in field of labor (Serbian: Odluka o Jedinstvenom kodeksu šifara za unošenje i šifriranje podataka u evidencijama u oblasti rada "Službeni glasnik RS", 56/2018)
3. Codebook of qualification level (Serbian: Šifarnik nivoa kvalifikacija), as stipulated by the Decision on Unique codex of codes for data entry and coding in records in field of labor (Serbian: Odluka o Jedinstvenom kodeksu šifara za unošenje i šifriranje podataka u evidencijama u oblasti rada "Službeni glasnik RS", 56/2018)
4. Codebook of occupations (Serbian: Šifrarnik zanimanja), as stipulated by the Decision on Unique codex of codes for data entry and coding in records in field of labor (Serbian: Odluka o Jedinstvenom kodeksu šifara za unošenje i šifriranje podataka u evidencijama u oblasti rada "Službeni glasnik RS", 56/2018)
5. ICD 10, International Classificatio of Diseases, 10th revision
6. ICD-O-3 the International Classification of Diseases for Oncology, version 3, revision 2 (2020), by World Health Organization & International Association of Cancer Registres International for
   i. Behavior Code for Neoplasms and
   ii. Morphology Codes
   iii. Histology types
7. Bethesda classification system for cervical and vaginal cytological diagnoses
8. Clark and Breslow staging for melanoma
9. TNM staging, American Joint Committee on Cancer, 8th Edition
10. Cancer data quality checks: common procedure for European cancer registries, ENCR, 2018