unofficial translation

Extension of the Automated Information System
for Primary Health Care
SIA AMP

TECHNICAL SPECIFICATIONS
for the development of the Cervical Screening Registry

Approved by the Ministry of Health, Labor and Social Protection of the Republic of Moldova (letter nr. 06/6859 as of 08.12.2020)

Name. Legal framework. Legal basis. Regulatory acts

The Automated Information System for Primary Health Care (SIA AMP) is meant to computerise the key duties and flows of medical, administrative and managerial staff of the Health Care Providers in the Republic of Moldova (hereinafter as Providers). SIA AMP also ensures the automated recording, control and coordination of the work of the Providers' key subdivisions, as well as the collection of the data necessary to inform the decision-making and process personal data, including those related to the health condition of those who benefit from health services.

The development of the system involved analysis work with the participation of external providers of software solutions, professionals from the Ministry of Health, Labour and Social Protection and from Providers. Currently, the system operates at the national level. The SIA AMP information system is hosted by the Government Cloud (hereinafter referred to as M-Cloud), and is maintained on an ongoing basis.

The applicable national law and the international conventions and treaties to which the Republic of Moldova is a party are the legal and regulatory basis of SIA AMP. The following laws and regulations govern SIA AMP development and operation:

- Law No 411 of 28 March 1995 on Health Care;
- Law No 982 of 11 May 2000 on Access to Information;
- Law No 1069 of 22 June 2000 on Computer Science;
- Law No 467 of 21 November 2003 on Computerization and State Information Resources;
- Law No 412-XV of 9 December 2004 on Official Statistics;
- Law 100-XV of 26 April 2001 on Civil Status Documents;
- Law No 71 of 22 March 2007 on Registrys;
- Law No 133 of 8 July 2011 on Personal Data Protection;
- Law No 142 of 19 July 2018 on Exchange of Data and Interoperability;
- Law No 143 of 19 July 2018 Amending and Supplementing Certain Legal Acts;
- Government of the Republic of Moldova Decision No 586 of 24 July 2017 approving the Regulation on Keeping Medical Registrys;
- Government Decision No 988 of 10 October 2018 approving the Rules on Primary Health Care Organization;
- Government Decision No 632 of 8 June 2004 approving the Policy for Building an Information Society in the Republic of Moldova;
- Government Decision No 1123 of 14 December 2010 approving the Requirements for Ensuring the Personal Data Security During Processing in Information Systems of Personal Data;
- Government of the Republic of Moldova Decision No 101 of 5 February 2008 establishing the State Registry of High-Security Medical Forms;
- Government of the Republic of Moldova Decision No 272 of 6 March 2002 on the Measures to Establish the 'State Registry of Legal Entities' Automated Information System;

- RM Government Decision No 1128 of 14 October 2004 approving the Concept of the Integrated Medical Information System;
- Government Decision No 128 of 20 February 2014 on Common Government Technological Platform (M-Cloud);
- Government Decision No 656 of 5 September 2012 approving the Interoperability Framework Program;
- Government Decision No 1090 of 31 December 2013 on the Governmental Electronic Service of Access Authentication and Control (MPass);
- Government Decision No 405 of 2 June 2014 on Integrated Governmental Electronic Service Digital Signature (MSign);
- RM Government Decision No 857 of 31 October 2013 on the National Strategy for Information Society Development 'Digital Moldova 2020';
- RM MoH Order No 695 of 13 October 2010 on Primary Health Care in the Republic of Moldova;
- MoH Order No 190 of 23 June 2003 establishing the Structure of District/Municipal Health Care System, stipulating the structure and duties of medical informatics and statistics departments of the public health care facilities;
- RM MoH Order No 828 of 31 October 2011 approving the Forms for Primary Medical Records;
- MoH Order on Development and Submission of Annual Medical Statistical Reports by Health Care Facilities, updated annually;
- MoH Order No 404 of 30 October 2007 on Legal Delimitation of Primary Health Care at District Level;
- Order No 1086 of 30 December 2016 approving the Framework Regulations on the Organisation and Operation of Health Care Providers;
- Order No 492/139A of 22 April 2013 on Medicines Reimbursed from the Compulsory Health Insurance Funds;
- Order No 727-494-a of 21 September 2016 approving the Regulation on the Organisation of Episodic Treatment at Treatment Rooms/Day Patient Departments, Procedure Rooms and Home, with Medicines Reimbursed from the Compulsory Health Insurance Funds, of the Most Frequent Diseases in the Family Doctor Practice;
- Order No 1080 of 28 December 2017 approving the Nomenclature of Public Primary Health Care Facilities at District Level;
- Order No 47 of 10 February 2016 approving the Nomenclature of Private Health Care Providers;
- Order No 466 of 11 June 2015 approving the Nomenclature of Hospital Health Care Facilities;
- MoH Order No 1023 of 29 December 2011 approving the Statistical Forms for Primary Medical Records;
- MoH Order No 1087/721 of 30 December 2016 approving the Regulation on the Registration of the Individual with the Family Doctor from the Health Care Facility Providing Primary Health Care under the Compulsory Health Insurance;
- Order No 515-130-A of 13 April 2018 on PHC Performance Indicators;
- MoH and NHIC Joint Order No 596/404A of 21 July 2016 Approving the Methodological Norms for the Implementation of the Single Program of Compulsory Health Insurance;

- MoH and NHIC Joint Order No 1131/658A of 29 December 2017 Approving the Criteria for Contracting the Health Care Facilities under the 2018 Compulsory Health Insurance System for 2018;
- Order No 87 of 01.06.2006 on the approval of technical regulation „Software lifecycle” RT 38370656 - 002:2006;

Objective of the Project

The system described below is subject to the procurement of software development services and formulates their technical, functional and non-functional specifications in order to roll out it in the Contractor's areas of interest. Specifically, this Project has the following components:

PROJECT STRUCTURE	DURATION / DEADLINE
Services for the development of the Cervical Screening Registry	Actual implementation period – 6 months after signing the contract.
User training services	The Provider shall deliver training services under this procedure.
Development of project related documentation	The Provider shall develop the project related documentation (project plan, analysis and design documents, testing plan, functional and performance test results, top OWASP vulnerabilities), complete users manuals and installing guidelines.
Installing the application on test and production environment	The Provider shall set up and install the application on test and production environment on the governmental platform MCloud
Ensuring support	The Provider shall ensure support activities throughout entire warranty period

Analysis document developed by the Provider shall be the first deliverable and will be subject to approval and acceptance by the Beneficiary. Analysis document approved by the Beneficiary shall be the reference for the Final Acceptance, governing over any other technical document. Analysis document shall be drafted by the Provider, involving the specialists of the Beneficiary, and will include:

- concrete details of the system architecture; sizing, infrastructure connections, security features, etc;
- data flows modelling, process design, logical interactions between system actors, details about the data;
- document templates, nomenclature;
- „use-case" cases, roles, access rights over entities;
- data types, table structure, connections between tables;
- application screens design;
- details regarding the connections with other systems: data types, programming of data exchange, access mode etc.

The system will be described both in terms of architecture and operation, and in this paper will be presented information on the technology used and how data are processed. The Provider will have access to the source code of the Contractor's system and will take all the risks arising from its modification. The services provided under this Project imply offering a warranty for the SIA AMP for a period of at least 12 months from the date the contract ends. In addition, the service Provider will document all the operations to modify the system and will submit them to the Beneficiary, offering a warranty to the whole system, starting with its development process and every time it intervenes in the system.

The initial chapters "SIA AMP overview" and "SIA AMP technical specifications" details everything thoroughly so that the potential bidders could assess accurately the effort, the necessary knowledge and their liability under this procurement.

SIA AMP overview

In order to understand the requirements of the Terms of Reference as accurately as possible, the Contractor informs the participants in the procurement about the technical specifications of SIA AMP. The Automated Information System for Primary Health Care is a national system of high complexity and strategic importance for the Health Care Service Providers in the Republic of Moldova, on the basis of which the Medical Registrys – the state information resource – are formed.

General characteristics of SIA AMP functioning

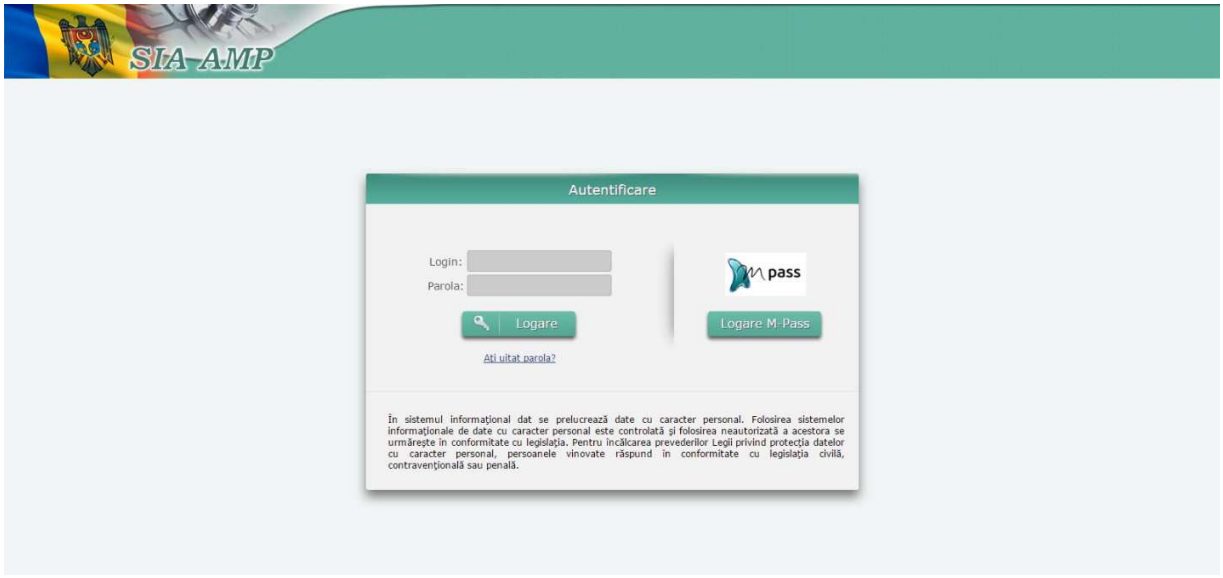
SIA AMP application has a 3-tier architecture, which allows its operation on the M-Cloud infrastructure. SIA AMP operates in a centralized manner on the hardware infrastructure designed for 99.9% availability and has the following general characteristics:

- covers the primary health care processes;
- can repair a module without affecting the others;
- complies with the applicable information technology standards;
- ensures flexibility to regularly adapt to the legal norms and to develop the software after its implementation;
- uses a service-oriented architecture to easily make new changes, with interventions only to the component to be updated, minimizing the costs and time required to make the changes;
- has a modern, high performance architecture, structured on 3 levels (database level, application level and access/user level);
- is meant to support a high number of clicks by users, both simultaneously and in short intervals;
- is scalable horizontally and vertically to settle the future changes in the number of users of the solution;
- recognizes correctly, accepts and integrates the information sources into the system;
- keeps the user interface, the content of Registrys, of databases and of generated documents in Romanian;
- allows the users to log in once to access all the modules of the application;
- aligns with the standards of information security and confidentiality and processing of personal data;
- ensures a high safety during its use.

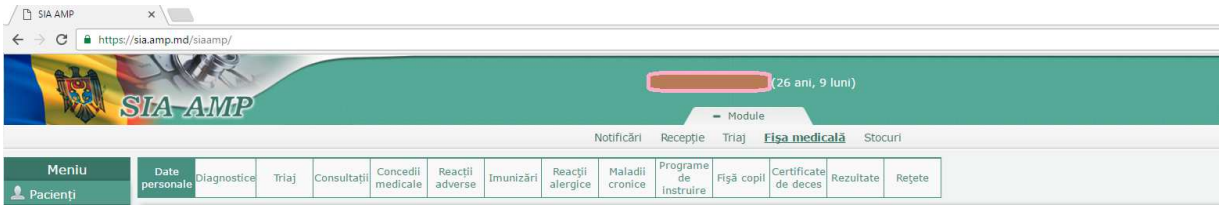
User interface

The interface is permanently accessible to all Providers in the Republic of Moldova.

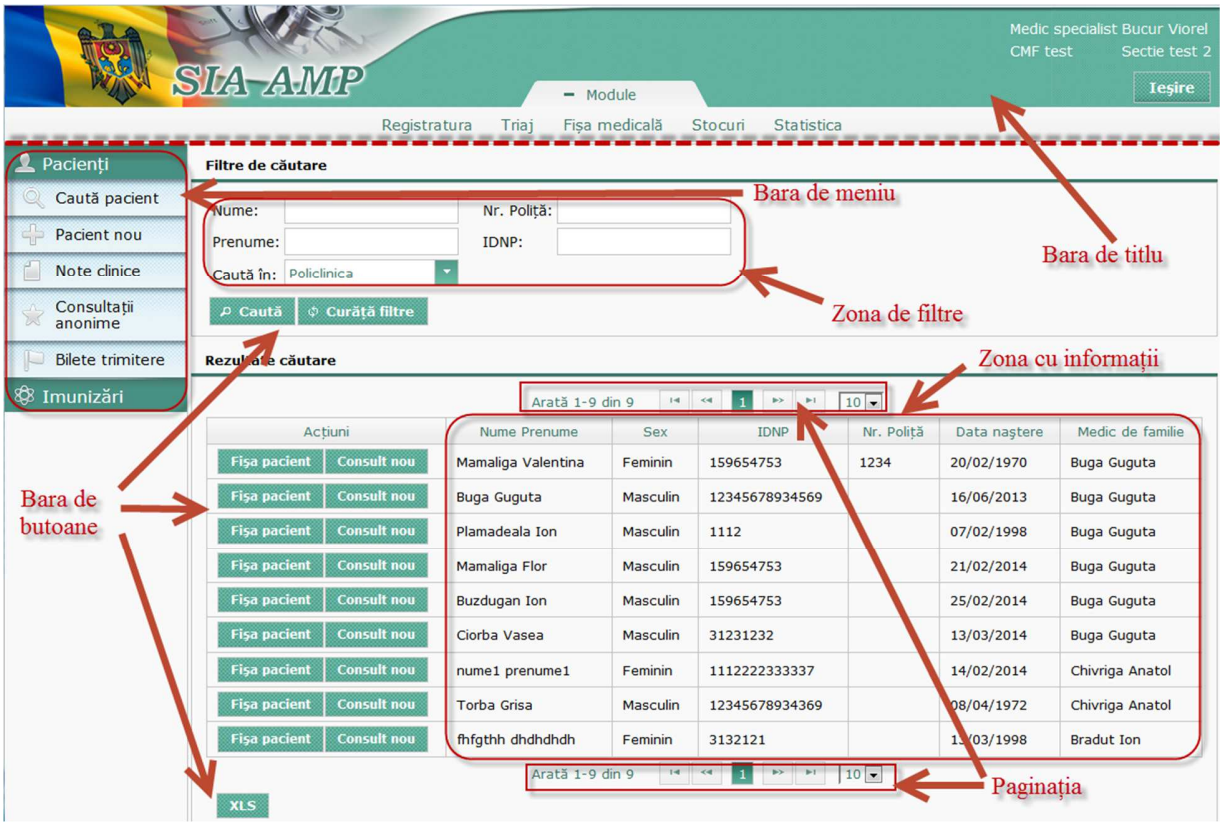
- SIA AMP has an intelligent, intuitive and user-friendly interface



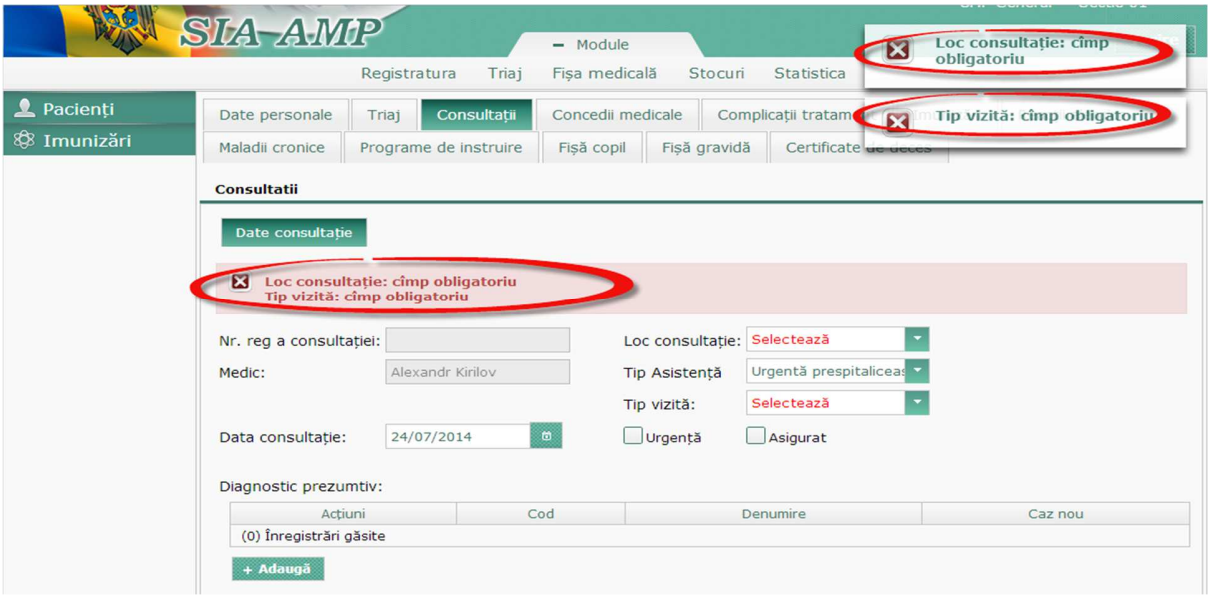
- the work interface is accessed from the web browser and does not require the installation of additional software components;



- the user interface is in Romanian;
- the interface allows alternative ways to enter medical data, i.e. by using the keyboard or the mouse;



- the information/warning messages are simple and do not require advanced technical knowledge.



Hardware and communication channels

The system has a hierarchical, client-server architecture with the following components:

- The hardware platform, consisting of the technical complex of data processing and transport, which takes place in the M-Cloud system. The M-Cloud platform ensures:

    - ✓ Redundantly protected servers for database hosting, system software and functional software (applications);
    - ✓ Communication equipment for the formation of local LAN networks and the organization of WAN territorial communications;
    - ✓ The provided servers have Intel x86/x64 family processors
    - ✓ The hardware platform provided by the beneficiary is properly sized to allow proper functioning of the system.
    - ✓ Optimal performance to achieve the objectives and ensure further rolling out of the system;
    - ✓ Flexibility in using the available means in order to receive information from external sources (other public institutions);
    - ✓ High level security of applications and data transfer;
    - ✓ Government information platforms' operating rules.

- The software platform has the following features:

    - ✓ Microsoft Windows, from the Enterprise series, is the operating system of the database servers and CentOS – of the application server;
    - ✓ Microsoft SQL Server is the database management system.
    - ✓ By default, there is a web browser on user stations.

Security system

The SIA AMP system operates in accordance with the security standards in force regulating information confidentiality and personal data processing. SIA AMP has the following characteristics:

- provides controlled user access to the database by diversifying the procedures of processing and viewing data according to each user's duties and responsibilities;
- is receptive to any changes in the list of users and/or rights granted to them regarding the execution of data processing procedures (entering, editing, deletion, viewing, etc.);
- is susceptible to any changes in the users' rights regarding the structural elements of the database, which are accessible to them;
- all user accounts are created by system administrators.
- includes data protection means in cases of system disturbances, unauthorized access, technical accidents;
- includes data protection when transporting it via networks.

Given the special nature of the information managed in SIA AMP, it has implemented a security mechanism that allows only authorized access to its components.

The system has the following security levels that ensure data confidentiality:

- Security at application level is ensured by the protocol on the communication between stations and the server; it is secure, HTTPS type with SSL Encryption Certificate;
- Security at business level is ensured by the system access module: unique authentication via the Governmental Electronic Service of Access Authentication and Control (MPass) and, on its basis, access to the appropriate level of data.
- Security at database level: MS SQL server database has its own security mechanism; access to information is made with the user/password, which are encrypted by default on the communication channel. Database integrity is ensured automatically, and changes to its structure are made solely on the basis of the corresponding rights of the database administrator. In addition, the database has its own backup mechanism, which allows in case of an accident to restore the latest versions (going back to several days). In correlation with the allocated M-cloud resources.

The system provides management and control of the access level, as well as identification and authentication rights for all objects. Access and authentication rights are created for each user group in the system; the system tracks the accessed information and functionalities. The system provides access to statistical data for certain groups of authenticated users. The system provides automatic verification of rights upon system authentication. Whenever the system is accessed subsequently, it creates an access log – an audit trail.

The following major types of users exist in the system:

- Administrator level: allows creating accounts, ensuring information security and other configurations.
- Operator level: - allows entering and modifying the data specific to its activity;

The system has data retention mechanisms, secure access and audit of actions:

- Data retention and version control. The system allows storing medical information (consultations, prescriptions, medical records) according to the legal requirements with all their versions through programmable backup operations.
- Security. In order to ensure security, all accesses to system comply with the access control rules in order to protect personal data. Security measures prevent unauthorized use of data and protect against loss, unauthorized modification and destruction of data in the system.
- Authentication. All users accessing the system are subject to the authentication process.
- Authorization to functionalities. The users who use the system are authorized to access the system functionalities on the basis of their identity, their roles in the system and the permissions associated with the user role(s).

- Authorization to data. The users who use the system are authorized to access the system functionalities on the basis of their identity, their roles in the system and the permissions associated with the user role(s). For example, a doctor has access only to his/her patients' electronic records.
- Non-repudiation. Non-repudiation is a way to ensure that a user cannot deny later that he/she has performed an operation. Non-repudiation is implemented through the following mechanisms:

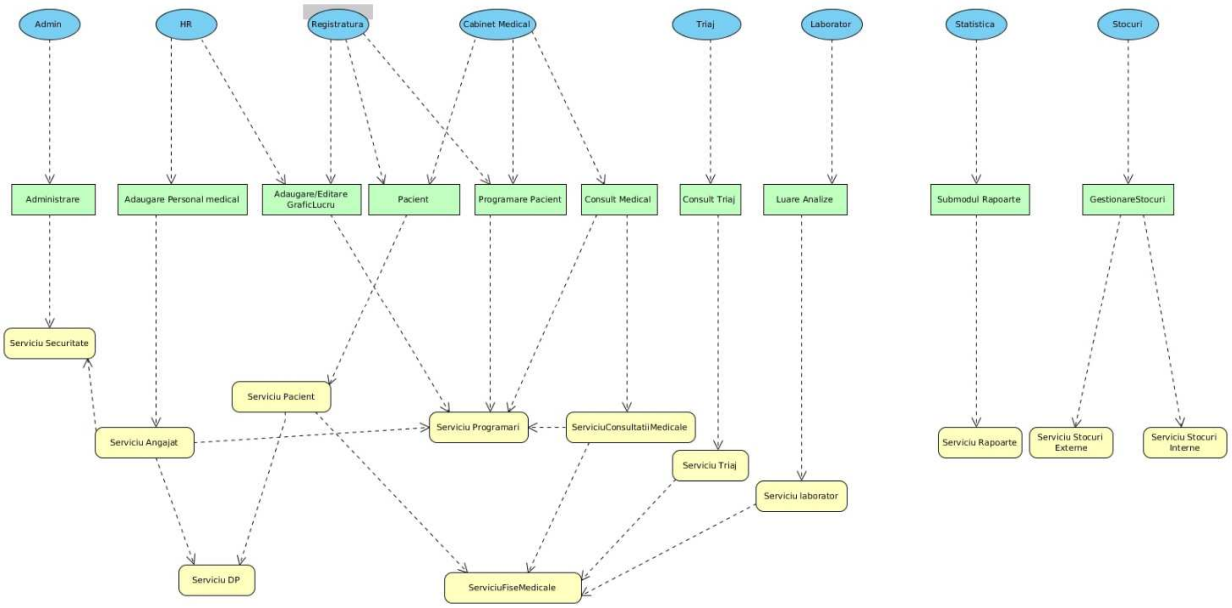
  ✓ User uniqueness in the system;
  ✓ Audit of all the operations carried out by the system;
  ✓ Version control mechanism for medical records.

- Secured data exchange. Any communication between the system and the outside world uses encryption methods both at the level of the communication channel and at the level of transmitted messages (SOAP messages).
- Audit. Any operation carried out by users or by other accessed systems is stored in the audit trail. It is thus allowed to investigate incidents by an administrator.

SIA AMP modules

The SIA AMP consists of a set of modules that cover various functionalities and have limited access depending on the role and access rights. The system's modules are:

- Human resources;
- Registry;
- Triage;
- Medical office;
- Laboratory;
- Statistics and Reporting;
- Stocks administration;
- Administration;



Modules of the Automated Information System for Primary Health Care

Human Resources module

This module is intended to uniformly manage human resources involved in primary care and specialized outpatient care (doctors, nurses, etc.). This manages personal data (identification, residence etc.), contact details of SIA AMP users.

Registry module

This module is intended to record patient appointments requesting medical consultation. This module the appointment date, the doctor, the institution and other data needed to make an appointment.

Triage module

This module is intended to enter data on the specific functionalities of the triage office of the primary medicine centers, preventive medical examinations etc.

Medical office module

This module is intended to uniformly manage patient data, to enter/view the information about patient visits (consultations, treatment, vaccinations etc.). The module provides access to the history of patient visits to family doctors, health professionals etc.

Laboratory module

This module is intended to manage the patients' medical examinations, requests and medical tests' results.

Statistics and Reporting module

This module is intended to generate operational statistics, ad hoc analysis. Each report has filtering criteria specific to each type of report. This module collects information from all the modules of the system: health staff, patients, medical offices etc., and generates centralizers, various statistics and reports.

In the Statistics and Reporting Module, the institutions to which the medical center is subordinated can generate reports with statistics on, doctors etc. Also, the module allows viewing some performance indicators.

Stocks administration module

This module is intended to manage the health facility's stocks, distribute consumables to departments and doctors and record the consumption made. The module manages invoices, inputs and outputs of the health facility's warehouse, entering data on goods quantity, unit price, date of production of the medicine, expiry date, etc. This module also allows users to obtain the current status of the existing stocks.

Contraceptives' record keeping module

Distribution Channel Table is used to record the name of the various locations of the medical network where contraceptives are distributed. Each record contains the name of the location, the unique registration code of the location, and the code of the person who usually supplies medical products for that location. At the same time, this module keeps record of quantitative indicators of contraceptive stocks and of patient-level distribution.

Administration and Audit module

This module is intended to perform the operations necessary for the normal functioning of the entire process. The module allows to manage the nomenclatures, users and other elements necessary for the operation of the SIA AMP. The system administration is divided into 2 parts:

- Administration of the application at general level
- Administration at local level

Administration of the application at general level includes:

- Administration of the security system.
- User data related to the use of the system.
- Definition of the user groups.
- Configuration of the users' access rights to various resources.
- Audit reports.
- Definition of the journaling actions.
- Management of the application nomenclatures (add, modify, delete, map with standard nomenclatures)
- Configuration of the connections with third parties (server IP and data to connect the application to the Population Registry, server IP and data to connect the application to NHIC).
- Management of the user accounts, which allows to add, modify, inactivate the corresponding registration to a user.

Local-level administration (module-specific) allows setting module-specific configurations:

- Registry - maintaining the registry with the costs of medical services and procedures.
- Medical office - administration of the National Immunization Programme, the immunization schedule.
- Laboratory - configuration of tests and parameters depending on the device used, test registry.
- Human Resources - management of the organization's infrastructure, organizational chart of the institution, departments, sections, positions and related nomenclatures.
- Stocks - maintaining the nomenclature of medicines and health care products, suppliers and units of measurement

This module also ensures identifying the actions performed by a user, chronologically. In case of an incident, the SIA AMP administrator can check the history of the operations performed by any user in order to identify and correct the problem. The SIA AMP records information on system authentications, patient records that have been accessed, type of access and printed information. For any type of data modification, SIA AMP records the time of the modification, the user who modified it and the changes made (the previous state is stored in a historical data table). Each record is versioned. The actions are audited regardless of whether the action was successful or not.

Services of SIA AMP development

Under this project, services of SIA AMP development refer to the initial functionalities of the Cervical Screening Registry and are part of a larger project, and at this stage the Contracting Authority requests analysis and development services with the following results:

Preamble

Organized cervical screening is a cancer prevention method by detecting and treating abnormalities at an early stage, which, if untreated, could develop into cervical cancer. The risk of invasive cervical cancer is reduced by 90% in women participating regularly in organized programs that use one of the two recommended screening tests. This means that 9 out of 10 invasive cancer cases can be prevented by screening. Taking part in the screening reduces significantly the risk of death from cervical cancer. Cervical screening is a complex multistep process that includes:

- Identification of the population to be screened.
- Information about and promotion of cervical screening among women to be screened, in order to raise the participation level.
- Screening recruitment (invitation).
- Individual guidance, personal risk assessment.
- Taking the cytological smear.
- Smear dispatch.
- Receipt of cytological smear result.
- Using the screening test result together with the person's history and clinical profile to determine and plan subsequent care.
- Follow-up the clinical recommendations and surveillance of women with abnormal cytology results over time.

In this context, it is important for doctors to ensure recruitment of women to be subject to cervical screening. It is absolutely necessary for the doctor to have the tools by which women can be recruited, by means of any communication channel (verbally, telephone, personal letter sent home, SMS, e-mail, messenger apps, active home visit, patient's visit to the health care facility).

The following services are involved in cervical screening:

- Primary health care;
- Cervical cytology;
- Colposcopy;
- Histology.

Women taking part in the cervical screening are examined in line with the Standard on Organization and Functioning of the Cervical Screening Service in the Republic of Moldova (SOP). According to the SOP, the asymptomatic women aged 25-61 years shall be invited for screening once every 3 years by family doctors, while asymptomatic women

diagnosed with HIV/AIDS or the ones under immunosuppressive therapy shall be invited once a year. If women do not show up for screening according to the recommended timeline, the doctors shall start the procedure of contacting women by available channels and reschedule them for another date, so that they could keep being part of the cervical screening program.

The recruitment process consists of an active, compulsory invitation of all women of primary and secondary level.

The purpose of this paper is to formulate a single vision on the development and implementation of the Cervical Screening Registry (hereinafter – the Registry), to substantiate and formulate the necessary legal and technical interventions, to raise the early detection of cervical cancer, to improve the cervical cancer morbidity and mortality indicators.

The Unit coordinating the cervical screening implementation shall use the Cervical Screening Registry to permanently plan, monitor, assess in pre-determined terms and coordinate the provision and promotion of cervical screening services. It shall also analyze data, create reports, monitor, calculate and analyze performance indicators, organize studies and generate annual and periodic statistical reports upon request.

The Registry uses incoming and outgoing documents. They will be updated according to the needs of the healthcare sector, in compliance with the legislation in force.

Incoming documents are forms 025/e, 203-1e, 203-2e, 232-1e, 232e, 233-1e, 233e, 234-1e, 234e, which will be Registryed by the Automated Information System Primary Health Care (SIA AMP). The Population Registry (form 166/e) with females aged 12 years, who can be vaccinated against HPV, will be another source of information.

Information space of the Cervical Screening Registry

This section comprises all the items, their attributes and scenarios that influence the information space of the Cervical Screening Registry and aims to define and provide an understanding of the system. Each data item below is characterized by the following peculiarities:

- uniqueness (the uniqueness of the item means the existence of the unique identifier, which distinguishes the given item from other similar items);
- state (the state of the item is defined by a set of attributes, which describe the variable properties of the item, considered in the system);
- behavior (the behavior of the item is described by the list of events occurring to the item and considered in the system),
- whether the item belongs to the system (i.e., it is initially considered and identified in the given system) or it is borrowed (i.e., it is taken together with the identifier from another system).

List of data items from the Cervical Screening Registry:

1) Individual person
– patient;
– patient without personal identification number (IDNO);
– doctor;
– sampler;
– laboratory technician.
2) Health care provider;
– Health care provider from the Republic of Moldova, both public and private who provides primary, specialized outpatient and hospital health care;
3) Investigation request:
   - Cervical cytology request form – 203-1/e;
   - Referral to colposcopic examination – 232/e;
   - Referral to histopathological investigation of the post-surgery material after hysterectomy – 233/e;
   - Referral to histopathological investigation in single or multifocal cervical biopsies/excisions – 234/e;
4) Investigation result:
   - Cervical cytological investigation result – 203-2/e;
   - Result of colposcopic examination – 232/e-1;
   - Result of the histopathological investigation of the cervical lesions in hysterectomy specimens – 233-1/e;
   - Result of histopathological investigation in single or multifocal cervical biopsies/excisions – 234-1/e;
5) Management recommendation depending on the cytological result – the system will analyze investigation results, and taking into account the patient history, will generate the management recommendation in accordance with the SOP (Standard for the operation and functioning of the cervical screening services in the Republic of Moldova);

Informational objects identifiers

1) The identifier of the informational object “Individual person” is the state identification number of the individual person (IDNO).
2) The identifier of the informational object “Health care provider” is the identification number of the Health care provider (IDNO).
3) The identifier of the informational objects “Investigation request” and “Investigation result” is a system-generated number.
4) The identifier of the informational objects “Management recommendation” is a system-generated number

Informational objects associated scenarios

The baseline scenario represents the list of events related to the informational objects registered in the Cervical Screening Registry, as follows:

1) Individual entity/Patient:

- Include in the list the eligible patients to be included in the screening programme;
- Include in the list the patients invited to screening;
- Record the patient include in the screening programme;
- Transfer of the patient to be recorded in Cancer Registry;

2) **Individual entity/Doctor, smear taker, laboratory staff;**
   - Record;
   - Modify the record;
   - Delete the record;
3) **Medical services provider;**
   - Record;
   - Modify the record;
   - Delete the record;
4) **Investigation request form;**
   - Initiate the form;
   - Transmit the form;
   - Receive and fill in the form;
5) **Investigation result;**
   - Develop, fill in the investigation result;
   - Transmit investigation result;
   - Develop the history of investigation results;
6) **Management recommendation:**
   - Generate recommendation;
   - Modify recommendation;
   - Delete recommendation;
   - Develop the history of recommendations;

Other scenarios/ functionalities:

7) **Creation of Lists:**
   - The general list of patients to be included in the programme;
   - The list of patients to be included in the programme in the current year. The patients that missed the appointment the previous year should be included in the list of patients for the current year;
   - Lit of the patients that were invited to appointments/investigations but missed them;
   - The list of patients that exceed the term for investigations;
   - The list of patients with pathologies, with investigations in accordance with the management algorithm.

8) **Creation of Notifications**:
   - Notification related to creation of lists on the need to invite the patients to appointments/investigations;
   - Notification sent to the Laboratory regarding submission of Investigation Request Form and transmission of the sample to the laboratory (pending form);
   - Notification sent to the smear taker/doctor that initiated the Form on the fact that the sample did not reach the laboratory;
   - Notification sent to the doctor and smear taker on the result of the sample;

- Notification sent to the doctor and smear taker in case the sample result was not received during one month;
- Notification sent the medical specialist (colposcopist) on the fact that there is a number of patients with positive results that should receive colposcopy services;
- Notification on investigation results;
- Other notifications;

9) **Appointment for health services:**
   - Appointment for colposcopy;
   - Appointment for routine screening. Family doctor/nurse makes the appointment for medical services;
   - Appointment for medical treatment;
   - Appointment for monitoring;

10) **Traceability of samples** – the circuit of samples between different service providers and actors involved in the screening programme;
11) **Calculation of performance indicators;**
12) **Drafting reports.**

Data of the 'Cervical Screening Registry' system

The system data represents all the attributes of the informational objects:

1) <u>data on the informational object "Individual person":</u>
   a) IDNO;
   b) person's identification data:
   – surname;
   – name;
   – date of birth;
   c) Home address and/or residency;
   d) Status of medical insurance;
   e) Number of medical insurance
   f) Contact data (tel. number, email);

2) <u>data on the informational object "Medical services provider":</u>
   a) IDNO of the health facility;
   b) Name of the health facility;

3) <u>data on the informational object "Laboratory":</u>
   a) IDNO of the laboratory health facility;
   b) Name of the laboratory health facility;

4) <u>data on the informational object "Pap test history":</u>
   a) Laboratory (IDNO, Name, Address);
   b) Test date;
   c) Result based on the classifiers (CIM10, Bethesda);

5) <u>data on the informational object "Cervical cytology request form – 203-1e":</u>

a) unique identifier;
b) identification data regarding the patient:
   - patient's IDNO;
   - patient's surname;
   - patient's name;
   - patient's date of birth;
   - number of patient's medical insurance;
   - patient's address;
   - patient's phone number;
   - patient's e-mail;
c) information about the medical services provider:
   - IDNO
   - Provider's name;
   - Provider's phone number;
d) Information about the smear taker:
   - IDNP;
   - surname;
   - name;
   - phone number;
e) clinical data:
– date of smear taken;
– date of last menstrual period;
– sampling site (cervix, vault);
– IUD (intrauterine contraceptive device);
– CP/COC/THS;
– HPV vaccination;
– Pregnancy;
– HIV positive;
– Viremia
– CD4
– Postmenopausal bleeding;
– Postcoital bleeding;
– Viewed cervix (Yes, No);
– Postpartum <12 weeks;
– Postmenopause;
– Total hysterectomy;
– Suspicious cervix;
f) collection of Pap tests history items;
g) electronic signature of the smear taker;
h) sample collection date;
i) patient's signature date;
j) Information about the laboratory
   - IDNO of the health facility that has a laboratory;
   - Name of laboratory (health facility);
   - Department of the health facility;
k) intact sample (Yes, No);
l) filled in form (Yes, No);
m) information about the laboratory staff (recorder);

- surname of the laboratory staff (recorder);
- name of the laboratory staff (recorder);
- signature of the laboratory staff (recorder);
- date and time of receipt in the laboratory;

n) information about primary examination:
- surname of the laboratory staff, primary examination;
- name of the laboratory staff, primary examination;
- date of the primary examination;
- result of the primary examination;
- electronic signature of the laboratory staff, primary examination;

o) information about the rapid examination:
- surname of the laboratory staff, rapid examination;
- name of the laboratory staff, rapid examination;
- date of the rapid examination;
- result of the rapid examination;
- electronic signature of the laboratory staff, rapid examination;

p) information about cytopathology examination:
- surname of the doctor-laboratory staff, cytopathology examination;
- name of the doctor-laboratory staff, cytopathology examination;
- date of the cytopathology examination;
- cytopathology examination result;
- electronic signature of the doctor-laboratory staff, cytopathology examination;

6) <u>data on the informational object “Cervical cytology investigation result - 203-2/e”:</u>

a) investigation result identifier;
b) identifier of the Cervical cytology request form;
c) information about the smear taker:
- smear taker IDNP;
- smear taker surname;
- smear taker name;
- IDNO of the medical facility;
- name of the medical facility;
- smear taker subdivision;
- smear taker phone number;

d) information about the patient:
- patient’s IDNP;
- patient’s surname;
- patient’s name;
- patient’s date of birth;
- patient’s address;
- patient’s phone number;
- patient’s e-mail;

e) Pap smear sampling date;
f) presence of cells in the transformation zone (Yes, No);
g) conclusion/ investigation result:
- UNSAT;
- UNSAT reason;
- NILM;
- ASC-US;

- ASC-US previous cellular abnormalities (Yes, No);
- ASC-H;
- LSIL;
- LSIL previous cellular abnormalities (Yes, No);
- HSIL;
- HSIL with suspected invasion;
- SCC;
- AGC;
- Endocervical AGC;
- NOS;
- ACG, endocervical/endometrial FN/FN/NOS;
- AGC, FN – with suspected invasion;
- Other malignant lesions/type/origin;

h) Simultaneous conditions (one or more values):
- Endometrial cells present in women ≥ 45 years;
- Trichomonas vaginalis;
- Herpes simplex virus;
- Cytomegalovirus;
- Candida spp;
- Actinomyces;

i) Management recommendation:
- Routine recall every 3 years;
- annual recall;
- repeat after 3 months,
- repeat after 6 months,
- repeat after 12 months;
- referral to colposcopy (14 days),
- referral to colposcopy (28 days),
- referral to the Institute of Oncology (7 days);

j) without further cytology;
k) information about the cyto-screener:
- surname;
- name;
- electronic signature;

l) date of the result;
m) family doctor's confirmation that the results have been communicated to the patient (Yes, No);
n) family doctor's electronic signature;
o) date of family doctor's electronic signature;

7) <u>data on the informational object "Referral to colposcopy examination – 232/e":</u>
a) identifier of investigation request;
b) identification data about the patient:
- patient's IDNP;
- patient's surname;
- patient's name;
- patient's date of birth;
- number of medical insurance;
- patient's address;

- patient's contact details (phone number, email);

c) information about the medical services provider:
   - Provider's INDP;
   - Provider's surname;
   - Provider's name;
   - Provider facility's IDNO;
   - Provider facility's name;
   - Provider's unit;
   - Provider's phone number;
   - Provider's e-mail;

d) date of the referral Pap test;
e) result of the referral Pap test;
f) clinical details;
g) previous colposcopy (Yes, No);
h) result of previous colposcopy;
i) previous treatment (Yes, No);
j) histological result;

8) <u>data on the informational object "Result of the colposcopy examination – 232/e-1":</u>

a) identifier of investigation request;
b) identifier of investigation result;
c) identification data about the patient:
   - patient's INDP;
   - patient's surname;
   - patient's name;
   - patient's date of birth;
   - number of medical insurance;
   - patient's address;
   - patient's contact details (phone number, email);
d) information about the family doctor/gynecologist that requested the investigation:
   - INDP of the family doctor/gynecologist who requested colposcopy;
   - surname of the family doctor/gynecologist who requested colposcopy;
   - name of the family doctor/gynecologist who requested colposcopy;
e) data about the medical services provider:
   - Health care provider's IDNO;
   - Provider's name;
   - Provider's unit;
f) Information on the appointment/referral:
   - primary patient with abnormal screening test result;
   - Symptoms;
   - Suspicious clinical cervix;
   - For treatment;
   - Monitoring visit;
g) Cytological referral result (ASCUS, LSIL, HSIL, ASCH, AGC, NOS, HSIL with suspected invasion, AGC FN);
h) Investigation history (ASCUS, LSIL, HSIL, ASCH, AGC, NOS, HSIL with suspected invasion, AGC FN):
i) High-risk oncogenic HPV status (positive, negative, unknown, identified HPV types);

j) Pregnant (Yes, No);
k) Pregnancies:
   - Number of pregnancies;
   - Number of childbirths;
l) parity 2;
m) UM data;
n) smoker (Yes, No);
o) heart diseases:
- No
- HTA
- ischemic heart disease
- valvular disease
- atrial fibrillation;
p) description of heart disease;
q) medications used;
r) contraception (Not used, COC/CP, Barrier);
s) other types of contraception;
t) known allergy (No, to lidocaine, to iodine, to latex);
u) known allergy, others;
v) immunodeficiency status (No, HIV, viremia, CD4, Iatrogenic (field for specification));
w) previous colposcopies:
- previous visits to colposcopy (No, Yes – untreated, Yes – treated)
- treatment date;
- colposcopy (Satisfactory, Unsatisfactory, Not performed);
- reason for unsatisfactory colposcopy;
- reason why colposcopy was not performed;
x) viewed squamo-columnar junction (Complete, Partial, Not visualized);
y) transformation zone (Type 1, Type 2, Type 3, congenital TZ);
z) when the 5% acetic acid solution was applied, the acetowhite reaction appeared within 30 seconds to 3 minutes;
aa) viewing (Fine punctuation, Coarse punctuation, Fine mosaicism, Coarse mosaicism);
bb) Abnormal colposcopic findings are recorded in the quadrant (I, II, III, IV);
cc) SWEDE Score Result (0,1,2,3,4,5,6,7,8,9,10);
   Observation: the system will include the mechanism for calculating the SWEDE score;
dd) Cervix:
– Not examined;
– Unsatisfactory colposcopy;
– Standard / Lack of any disease;
– Signs of infection/inflammation;
– Low-grade cervical lesion;
– High-grade cervical lesion;
– Glandular lesion (AIS);
– Invasion;
– Polyp;
– Ectropion;

– Others;

ee) Vagina:

– Not examined;
– Unsatisfactory vaginoscopy;
– Reason for unsatisfactory vaginoscopy;
– Standard / Lack of any disease;
– Signs of inflammation/infection;
– Low-grade VAIN;
– High-grade VAIN;
– Invasion;
– Others;

ff) Vulva:

– Not examined;
– Unsatisfactory vulvoscopy;
– Reason for unsatisfactory vulvoscopy;
– Lack of any disease;
– Lichen sclerosus et atrophicus/dystrophy;
– Inflammation;
– Low-grade VIN;
– High-grade VIN;
– Invasion;
– Others;

gg) Biopsy:

- biopsy taken (Yes, No);
- type of biopsy (punch-biopsy);
- punch-biopsy type value;
- other type of biopsy;
- method used (Loop electrosurgical excision procedure (LEEP), Cryotherapy, Diathermocoagulation);
- type of excision (Type 1 (7-10 mm), Type 2 (10-15 mm), Type 3 (>15 mm));
- anesthesia (No, Local, General);
- General anesthesia - reasons (Large lesion, High risk of bleeding, Patient anxiety, Difficult access, Other interventions were needed);
- complications (No, Bleeding, Injuries to adjacent organs, Others);
- complications, others;
- number of excised tissue samples;
- number of excised tissue samples - Reasons (Large lesion, Difficult access, Doctor's decision);

hh) Management recommendations:

- multidisciplinary discussion (Yes, No);
- colposcopic treatment (Yes, No);
- colposcopic monitoring (consultation over 1 month, consultation over 2 months, consultation over 2 months, consultation over 6 months, consultation over 12 months);
- colposcopic monitoring, others;
- AMP monitoring (cytology over 6 months, cytology over 12 months, annual recall during 4 years, annual recall during 9 years, annual recall, routine screening);
- AMP monitoring, others;

- referral to the gynecologic oncologist/Institute of Oncology (Yes, No);

ii) electronic signature of the doctor;

jj) date of the examination result;

kk) Free field for text with colposcopic conclusion or recommendations.

9) data on the informational object “Referral to histopathological investigation of the post-surgery material after hysterectomy – 233/e”:

a) referral form identifier;
b) patient’s surname;
c) patient’s name;
d) patient’s date of birth;
e) patient’s age;
f) patient’s address;
g) patient’s IDNO;
h) patient’s insurance policy No;
i) patient’s phone number;
j) patient’s e-mail;
k) Health care provider’s IDNO;
l) Provider’s name;
m) Provider’s section;
n) medical record No;
o) family doctor’s surname;
p) family doctor’s name;
q) diagnosis;
r) description of the part sent;
s) date of collection;
t) fastening method;
u) requested examination;
v) surgeon’ surname;
w) surgeon’s name;
x) UM;
y) menopause (Yes, No);
z) previous colposcopy (Yes, No);
aa) previous treatment (Yes, No);
bb) description of previous treatment;
cc) surname of the laboratory technician who received the sample;
dd) name of the laboratory technician who received the sample;
ee) signature of the laboratory technician;
ff) date of referral;

10) data on the information item (Result of the histopathological investigation of the cervical lesions in hysterectomy specimens – 233-1/e);

a) identifier of investigation request;
b) identifier of investigation result;
c) identification data about the patient:
   - patient’s INDP;
   - patient’s surname;
   - patient’s name;
   - patient’s date of birth;

- number of medical insurance;
- patient's address;
- patient's contact details (phone number, email);

d) information about medical services provider:
- IDNO;
- Provider's name;

e) date of receipt;
f) date of medical conclusion;
g) number of medical conclusion;
h) pathologist's surname;
i) pathologist's name;
j) surgeon' surname;
k) surgeon's name;
l) Vaginal cuff (present, absent);
m) length;
n) diameter;
o) dimensions of uterus:
– size;
– transverse;
– anteroposterior;
p) adnexa (presence, absence, normal, abnormal);
q) details of abnormal adnexa;
r) no tumour seen;
s) maximum dimension of tumour 1;
t) maximum dimension of tumour 2;
u) position of cervical tumour (anterior, posterior, right, left, circumferential, ectocervix, endocervix);
v) macroscopic involvement of vagina (Yes, No);
w) macroscopic involvement of parametria (Yes, No);
x) macroscopic involvement of paracervical tissue (Yes, No);
y) type (squamous carcinoma, adenosquamous carcinoma, adenocarcinoma, neuroendocrine carcinoma, other);
z) type specification;
aa) differentiation (high/grade 1, moderate/grade 2, poor/grade 3, not applicable);
bb) maximum horizontal dimension of the tumour;
cc) thickness/depth of invasion (as appropriate);
dd) Maximum dimension of cervical stroma involvement (Minimum dimension not affected);
ee) Its positioning;
ff) The closest radial resection margin (Including paracervical tissue thickness);
gg) Its positioning;
hh) Vaginal involvement (Yes, No);
ii) Distance from distal vaginal epithelial margin;
jj) Its positioning;
kk) Paracervical involvement (Yes, No, Left, Right);
ll) Parametrial involvement (Yes, No, Left, Right);
mm) Lymphovascular invasion (Yes, No);
nn) CIN (present, absent);
oo) Grade 1/2/3

pp) CGIN (present, absent);
qq) SMILE (present, absent);
rr) Total number:
– right;
– left;
– iliac;
– right;
– left.
ss) Number of those involved:
– right;
– left;
– iliac;
– right;
– left.
tt) extranodal spread (Yes, No);
uu) Para-aortic nodes (positive, negative, not sampled, Total number, number of positive nodes);
vv) extranodal spread (Yes, No);
ww) normal endometrium;
xx) abnormal endometrium;
yy) normal myometrium;
zz) abnormal myometrium;
aaa) normal right adnexum;
bbb) abnormal right adnexum;
ccc) normal left adnexum;
ddd) abnormal left adnexum;
eee) provisional pathological FIGO stage;
fff) pTNM stage:
– pT;
– pN;
– M.
ggg) SNOMED code:
– T1;
– M1;
– T2;
– M2;
hhh) diagnosis;
iii) signature of pathologist;
jjj) data of the result.

11) Data on the informational object “Referral to histopathological investigation in single or multifocal cervical biopsies/excisions – 234/e”:
a) identifier of investigation request;
b) identification data about the patient:
- patient’s INDP;
- patient’s surname;
- patient’s name;
- patient’s date of birth;

- patient’s age;
- number of mandatory medical insurance;
- patient’s address;
- patient’s contact details (phone number, email);

c) information about medical services provider:
- IDNO;
- Provider’s name;
- Provider’s section;
- medical record No;

d) Pap test date;
e) Pap test result;
f) clinical details;
g) previous colposcopies (Yes, No);
h) previous treatment (Yes, No);
i) details about previous treatment;
j) previous histological result;
k) current colposcopy conclusion;
l) date of current colposcopy;
m) indications for biopsy/excision;
n) biopsy taken (Yes, No);
o) type of biopsy:
– punch-biopsy;
– another;
p) Method used:
– Loop electrosurgical excision procedure (LEEP);
– Cryotherapy;
– Diathermocoagulation;
q) Type of excision (Type 1 (7-10 mm), Type 2 (10-15 mm), Type 3 (>15 mm));
r) Number of pieces (1, 2, 3);
s) Doctor's surname;
t) Doctor's name;
u) Signature of doctor;
v) Date of referral.

12) <u>Data on the informational object “Result of histopathological investigation in single or multifocal cervical biopsies/excisions – 234-1/e”:</u>

a) identifier of investigation request;
b) identifier of investigation result;
c) identification data about the patient:
- patient’s INDP;
- patient’s surname;
- patient’s name;
- patient’s date of birth;
- number of medical insurance;

d) information about medical services provider:
- IDNO;
- Provider’s name;
- Provider’s section
- Data of receipt;

e) date of medical conclusion;
f) Number of medical conclusion;
g) pathologist's name;
h) pathologist's surname
i) surgeon' surname;
j) surgeon's name;
k) description of specimen and macroscopic data (Wedge, Cone, Loop);
l) Loop:
– dimension 1;
– dimension 2;
– thickness/depth;
m) number of fragments;
n) dimensions of each and in aggregate;
o) invasive malignancy type (squamous carcinoma, adenosquamous carcinoma, adenocarcinoma, adenocarcinoma, other, description);
p) differentiation of invasive carcinoma (Well/Grade 1, Moderate/Grade 2, Poor/Grade 3, Not applicable);
q) distribution of invasive component (Unifocal, Multifocal);
r) maximum horizontal dimension of tumour;
s) maximum thickness/depth of invasion;
t) presence of invasive foci in three consecutive sections (Yes, No);
u) CIN (present, absent);
v) CIN grade (CIN 1, CIN 2, CIN 3);
w) CGIN (present, absent);
x) CGIN grade (low, high);
y) SMILE (present, absent);
z) ectocervical resection margin (not involved, involved);
aa) ectocervical resection margin specifications;
bb) endocervical resection margin (not involved, involved);
cc) endocervical resection margin specifications;
dd) deep lateral/radial resection margin (not involved, involved);
ee) deep lateral/radial resection margin specifications;
ff) lymphovascular space invasion (present, absent);
gg) provisional pathological FIGO stage;
hh) pTNM stage:
- pT;
– pN;
– M.
ii) SNOMED code:
– T1;
– M1;
– T2;
– M2;
jj) diagnosis;
kk) signature of pathologist;
ll) date of the result;

13) <u>data on the informational object</u> "<u>Management recommendation":</u>

a) name of recommendation (will be automatically generated depending on the result);
b) recall:
– routine (every 3 years);
– annual from 25 years old;
– repeat at (6, 18; 30) months (2.5 years monitoring in total);
– repeat at (6, 12) months and then annually for 4 years (five-year monitoring in total);
– referral to colposcopy;
– repeat Pap test in 3 months;
– repeat after 3 months or referral to gynecologist if it is difficult to obtain a satisfactory smear;
– repeat Pap test after 5 months;
– referral to colposcopy within 14 days;
– referral to colposcopy within 7 days;

General Remark: The result note will contain only the values related to the patient concerned and the recommendation, which will be clearly emphasized.

Use of Classifications

To ensure authenticity and to reduce the volume of information stored in the system, a classification system will be used. Thus, at least the following classifications will be used:

1. International Classification of Diseases ICD-10-WHO;
2. International Classification of Diseases for Oncology ICD-O-3;
3. Classification of Health Care Providers;
4. 2014 Bethesda System for reporting cervical cytology results adapted for use in the Republic of Moldova according to SOP;
5. TNM and FIGO Staging of Cervical Cancer according to SOP;
6. TNM Classification of Cervical Cancer according to SOP;

To make sure that the informational resource of the Cervical Screening Registry is developed properly, it will be necessary to ensure its interoperability with the following informational resources:

- IS “State Registry of Population” – to use data on natural persons;
- IS “State Registry of Legal Entities” – to use data on legal entities;
- IS “Primary Health Care” – to use data on the family doctor, health care services provider, laboratories;
- IS “Hospital Health Care” – to use data on doctors, health care services provider.

Cervical Screening Registry will use the following government platform services:

- MPass electronic service for authentication and access control – to organize the log in and access of users in the system;
- MSign electronic signature governmental service – to sign the documents of the system;

- MConnect interoperability platform – to ensure data exchange with other informational resources;
- MLog logging and audit service – to log important events produced in the system;
- MNotify electronic notification governmental service – to ensure the notification process.

Cervical Screening Registry Module – extension of SIA AMP functionalities as follows:

	Functionality	Description. Expected results
1	**Family doctor**	Module intended for the family doctor
1.1	Establish a countrywide database of patients;	Implement in SIA AMP mechanisms that would select patients eligible for screening Registry. The mechanism must be dynamic, taking into account the age of the patients and the current date. The system must have a history mechanism to facilitate access to dynamic historical data. The expected amount of data will be correlated with the following indicators: - 330 000 – patients annually - 363 000 – cytology tests per year - 63 000 – colposcopies per year The tests will be processed in approximately 14 laboratories. The module should allow encryption of database tables and columns, in order to ensure a high level of personal data protection. *Location in SIA AMP – Medical Office Module*
1.2	Implement mechanisms to notify patients about various actions or events	The module must have a mechanism to select patients that are eligible for screening, according to various criteria established by the user. The notification mechanism must be based on the rules set in Annex 2. The module must have a notification mechanism (e-mail, SMS, etc.). Notifications must be generated by the user and/or administrator. They will be recorded in the database. The user must be able to check at any time the list of eligible patients and their status, as follows: a. Selected patient b. Notified patient (notification type) c. Number of notifications sent d. No response (feedback) e. Patient contacted by telephone (appointment made/refused appointment) f. Examined patient. Status information and screening appointment will be visible in the patient record. The system must include a notification mechanism for the family doctor when accessing the medical record. The following lists will be included in the report module:

	Functionality	Description. Expected results
		1. Women from List 1. The total list of women eligible for screening in the current year / required period. 2. Women from List 2. The total list of women that were not screened during the past two years / required period. The doctor must have the possibility to exclude eligible people from the list (pointing out the reason). If the person is eligible, but she has not been in the country for a long time, it does not make sense to keep this person on the list. The doctor must be able to access the list of excluded people and add them back to the list (if the person returns after a while). The security module will have an embedded competence that can grant access to the notifications module to the users appointed by the beneficiary. On the basis of access right, the user will be able to generate a screening invitation (printable document) to the patient that is eligible under the screening program. *Location in SIA AMP – Medical Office Module*
1.3	Implement the examination – extension form	A specific screening section will be added to the examination form, which will be available only to the eligible patients. This section will contain the fields from the forms described above. After filling in the mandatory fields, the system will allow generating the cervical cytology sampling form, which will include both elements of the aforementioned forms and a unique system-level identifier. It will consist of 2 letters and 4 digits. E.g.: AA1234. *Location in SIA AMP – Medical Office Module*
1.4	View results	In SIA AMP, section 025 of the medical record, test history, the family doctor will view the result note issued by the laboratory that processed the sample. *Location in SIA AMP – Medical Office Module*
1.5	SIA AMP Notification Module	A special module will be developed for family doctors, which will generate alerts when a result is positive. Basically, the family doctor, after the authentication in the system will receive a series of alerts with receipt confirmation for the appointed patients and established events. *Location in SIA AMP – Administration Module*
2	**Triage/Registry Module**	

	Functionality	Description. Expected results
2.1	Notify the patients	A new function that will generate notifications at centralized level for all the patients that are served by the primary health care facility and that meet the eligibility criteria will be developed under the Triage Module. The system will use interconnection mechanisms, through which it will update in real time the list of appointments – patient/family doctor At the same time, if a patient changes his/her family doctor, the system should automatically transmit the status from the screening Registry. The status for the notifications issued will be filled in for each patient individually. *Location in SIA AMP – Administration Module* *Location in SIA AMP – Registry Module*
2.2	Monitor the activity	The system will have a centralized mechanism for monitoring the notification/appointment of patients for screening Users will be able to view the status for the section 'Management Recommendations' of the cytological examination. *Location in SIA AMP – Administration Module*
3	**Laboratory**	Extending the functionalities of the Laboratory Module
3.1	Security	The Laboratory Module will be available for laboratories performing cytological investigations. The system will generate different entities for each laboratory. This process should be configurable and specific to the global administration component. The access to this service will be allowed only on the basis of MPass and authorizations from the beneficiary of NHIC/ MoH. The access will be configurable in the security component. The system administrator will grant access on the basis of the law in force. *Location in SIA AMP – Laboratory Module*
3.2	Implement mechanisms for referring to tests and receiving test results;	The system will generate a document classifying all the samples collected, which will contain the following information: 1. patient's IDNO 2. Name and surname 3. Sample unique identifier 4. Patient's family doctor 5. Phone/email 6. Sampler's name and surname; 7. Sampler's phone number/e-mail; 8. Sample collection date

	Functionality	Description. Expected results
		The collected samples will be accompanied in the laboratory by this document. *Location in SIA AMP – Laboratory Module*
3.3	Implementation – cytology	Allow the advanced search of requests for cytology laboratory tests on the basis of the unique code; Allow viewing specific and pathological results; Allow the 'bulk' processing of the requests received; Allow the detailed editing of requests for laboratory tests – cytology; Provide modern ways of tracking the status of an application; Provide modern ways of editing the results; Protect the information from changes made by unauthorized persons; *Location in SIA AMP – Laboratory Module*
3.4	Edit the result	In SIA AMP, the laboratory, on the basis of the unique identifier, will access the requests for cytological examination and will be able to edit the result. The system will provide the laboratory doctor with a working section, which will contain a range of predefined fields according to the above mentioned specifications. The pre-filled section will contain business rules in line with the relevant standards. The result note will contain only the filled-in values, as well as the related explanations, where applicable. The system should allow implementing the result templates – explanations, predefined text, etc. *Location in SIA AMP – Laboratory Module*
3.5	Laboratory reports	The system will provide a set of reports that can be configurable for investigations conducted under the screening program. The access to reports and investigations will be established by the general administrator of the system. *Location in SIA AMP – Laboratory Module*
3.6	Interoperability	The developer will create an interoperability interface for the laboratories that already have an IT system. This is necessary both to send the investigation requests and to receive the result notes. All the communication activities should be performed in accordance with the law in force. *Location in SIA AMP – Administration Module*
4	**Specialist doctor**	
4.1	Specialist examination	In the section 'Specialist doctor' the system should allow to conduct a specialized examination, both on the basis of the referral from the family doctor and direct visits *Location in SIA AMP – Medical Office Module*
4.2.	Examination form – extension	A specific screening section will be added to the examination form, which will be available only to the

	Functionality	Description. Expected results
		eligible patients. With the help of this section, the specialist doctor will be able to view the status of the patient in the screening Registry. At the same time, the specialist doctor will have access to the history of cytological examinations. - After filling in the mandatory fields of the examination form, the system will allow to generating the cervical cytology sampling form, which is going to include both elements of the aforementioned forms and a unique system-level identifier. It will consist of 2 letters and 4 digits. E.g.: AA1234. Once the cytological examination is done, data about it will be available in the medical record. The family doctor of the patient, but also to the specialist doctor have access to this information. *Location in SIA AMP – Medical Office Module*
4.3	Examination form – colposcopic examination	A new type of examination will be developed under the system – colposcopic examination It must contain time sections like DDL, Radio Button, Free text. Following the colposcopic examination, the specialist doctor must be able to upload in the system a series of pictures from the investigation equipment. The system limit is 5 files with a maximum size of 3 Mb each. *Location in SIA AMP – Medical Office Module*
		During the colposcopic examination, the doctor will take a sample for biopsy and will send it to the laboratory of pathological anatomy for microscopic and histological examination. - A sampling form will be generated within the system and it will contain an unique identifier consisting of 2 letters and 4 digits. E.g.: AA1234. The sampling form will be issued only after all the mandatory fields are filed according to the protocol. *Location in SIA AMP – Medical Office Module*
5	**Laboratory of pathological anatomy**	Extend the functionalities of Laboratory Module
5.1	Security	The Laboratory Module will be available to all the laboratories that conduct investigations for pathological anatomy. The system will generate different entities for each laboratory. This process should be configurable and specific to the global administration component. The access to this service will be allowed only on the basis of MPass and authorizations from the beneficiary of NHIC/ MoH. *location in SIA AMP – Laboratory Module*

	Functionality	Description. Expected results
5.2	Implement mechanisms for referring to tests and receiving test results;	The system will generate a document classifying all the samples collected and will contain the following information: 9. patient's IDN 10. Name and surname 11. Sample unique identifier 12. Colposcopist who collect the samples 13. Sample collection date 14. Phone/email The collected samples will be accompanied in the laboratory by this document. *location in SIA AMP – Administration Module*
5.3	Implementation – Pathological Anatomy	Allow the advanced search of requests for pathological anatomy laboratory tests on the basis of the unique code; Allow viewing specific and pathological results; Allow the 'bulk' processing of the requests received; Allow the detailed editing of requests for laboratory tests – pathological anatomy; Provide modern ways of tracking the status of an application; Provide modern ways of editing the results; Protect the information from changes made by unauthorized persons; *location in SIA AMP – Laboratory Module*
5.4	Edit the result	In SIA AMP, the laboratory, on the basis of the unique identifier, will access the requests for examination and will be able to edit the result. In the Laboratory sections, based on the unique identifier, the doctor will have access to a series of information from the patient's record as follows: - Referral form to cytology - Referral form to colposcopy - Referral form to histology - Result note: cytology, colposcopy, histology Access to medical information will be done in accordance with the legal provisions in force. The system will provide the laboratory doctor with a working section, which will contain a range of predefined fields according to the regulations in force. The pre-filled section will contain business rules in line with the relevant standards. The result note will contain only the filled-in values, as well as the related explanations, where applicable. The system should allow implementing the result templates – explanations, predefined text, etc. The system should allow to upload and store pictures related to the result note.

	Functionality	Description. Expected results
		The system limit is 5 files with a maximum size of 3 Mb each. *location in SIA AMP – Laboratory Module*
5.5	Laboratory reports	The system will provide a set of reports that can be configurable for investigations conducted under the screening program. The access to reports and investigations will be configurable. The system administrator grants the access on the basis of the law in force. *location in SIA AMP – Laboratory Module*
6	**Electronic signature**	The system will include a mechanism for electronic approval/signing of the documents in the system, by integrating the MPass service
7	**Analysis of Cervical Screening Registry Module – Reporting**	It is a module intended for the screening department to be used for planning, assessing and coordinating the processes. It will have access to the reporting system and will be able to perform a series of queries in the database. The structure of the reports is described in detail in the Annex 1 *Location in SIA AMP – Statistics Module*
8	**Visual identity**	As regards the described functionalities (for example the location/grouping of the buttons, dropdown, menus, etc.) in this term of reference, the provider used the visual identity within the SIA AMP.
9	**Application ergonomics**	The Provider will implement a series of mechanisms to optimize the experience of working with the system. For example, minimize the number of clicks while using the nomenclatures, automatic completion, navigation through the page with the TAB button and saving the data by pressing the ENTER key.
10	**Communication module Interoperability**	The Provider will develop a communication module independent from SIA AMP platform. It will automatically retrieve data from SQL databases, standardize them and send them via WS through the M-connect platform to other entities / systems. At the same time, the module will be able to take standardized data and transmit them through the WS mechanism (M-Connect) and transpose them into SQL databases. The technical specifications of the forms to be submitted will be defined in the analysis stage. The fields, as well as the business rules, are defined in the medical forms in force, used today in lettered format.
11	**Interconnection with external systems**	The system should allow interconnection with other systems. The data exchange must be bidirectional. The reference system (nomenclatures) used will be the one published by the Ministry of Health, Labor and Social

	Functionality	Description. Expected results
		Protection on the date of signing the contract. For example, the Form 027e. Interoperability mechanism will observe the M-Connect standards. The systems included in the interoperability system are the following: 1. SIA AMS 2. Cancer Registry 3. DRG-Online
12	**New Registrys and reports in SIA AMP**	The system must automatically complete the following Registrys: Registry for the registration of taken smears; Registry for the registration of cytological analysis; Registry for the registration of colposcopic investigations; Registry for the registration of histopathological analysis; Statistical report on data and specific diseases Registryed during the cervical screening. Observation: reporting template might be changed. At the analysis stage, the final approved version will be requested from the Ministry of Health Labor and Social Protection on the date of signing the contract. Within the system, reception, transmission and reporting mechanisms will be implemented for the following forms: 203/e, 203-2/e, 232-1/e, 232/e, 233-1/e, 233/e, 234-1/e, 234/e.

Interoperability and functional space

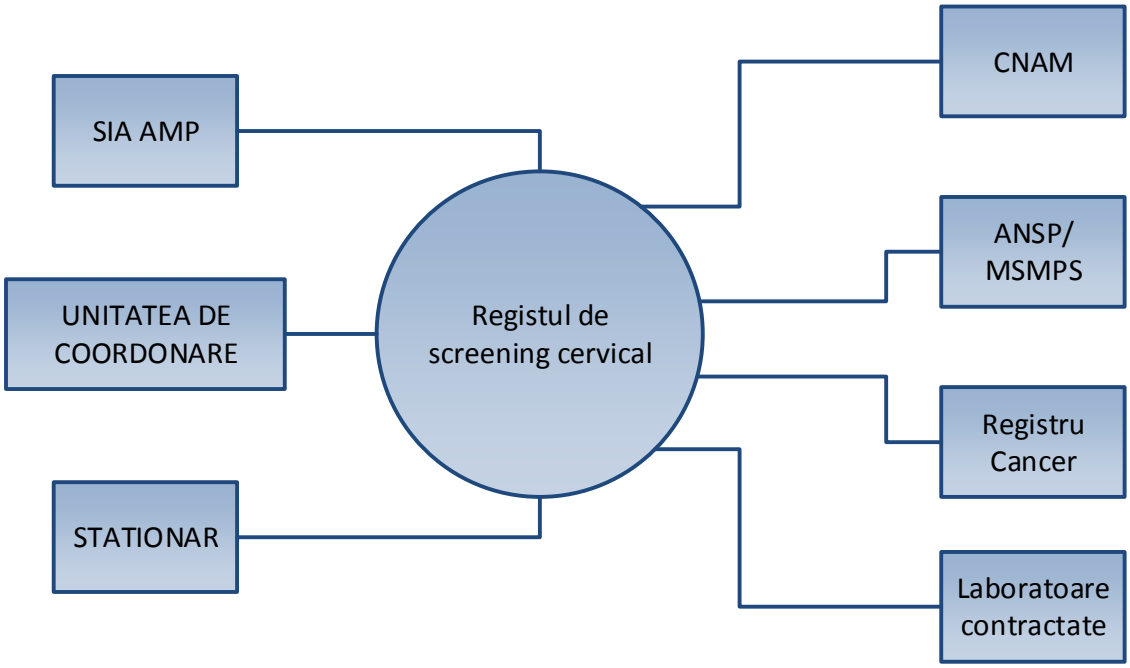


Figure 1 – Interconnection of the Cervical Screening Registry with other ISs

The Cervical Screening Registry comprises all software, hardware, information, organization, data transmission systems, data use technology, legal provisions and infrastructure needed to support the information activity.

Programming language and technologies used for the development of the Cervical Screening Registry should be compatible with both SIA AMP and SIA AMS technology stack:

- SIA AMP was developed using Java EE, JSF, Prime faces, jQuery, EJB, CDI, EclipseLink, JPA, JDBC, EHCache;
- SIA AMS was developed using ASP classic and some functionalities using ASP.NET.2.0.

Proposed technologies shall be approved by the Beneficiary.

Property rights

The Beneficiary (Ministry of Health, Labor and Social Protection) has the ownership rights on the code of the application. Any change to the code results in a new version of the application for which the contracted Company shall provide full warranty. The Beneficiary will keep the ownership rights on the application. For a clear understanding, changes to the existing functionalities or new developments of the application shall be made at the request of the Beneficiary. The beneficiary shall not interfere with the code of the application, which is why the contracted Company shall be responsible for the correct operation of the application during and after making changes to the code. Any change in

the application shall oblige the contracted Company to give a warranty for the entire system and not just for the changes made. The Beneficiary shall continue to keep the ownership rights on the entire application regardless of the changes made throughout the contract period.

Functional space of the Cervical Screening Registry

The main functions of the Cervical Screening Registry are listed below:

1) record information about patients aged 24-62 years;
2) ensure logical checks of recorded medical data, in line with the legislation in force;
3) generate alerts and notifications regarding scheduled appointments;
4) gather and store information in the database of the Cervical Screening Registry;
5) ensure data exchange with other state institutions through the M–Connect interoperability platform;

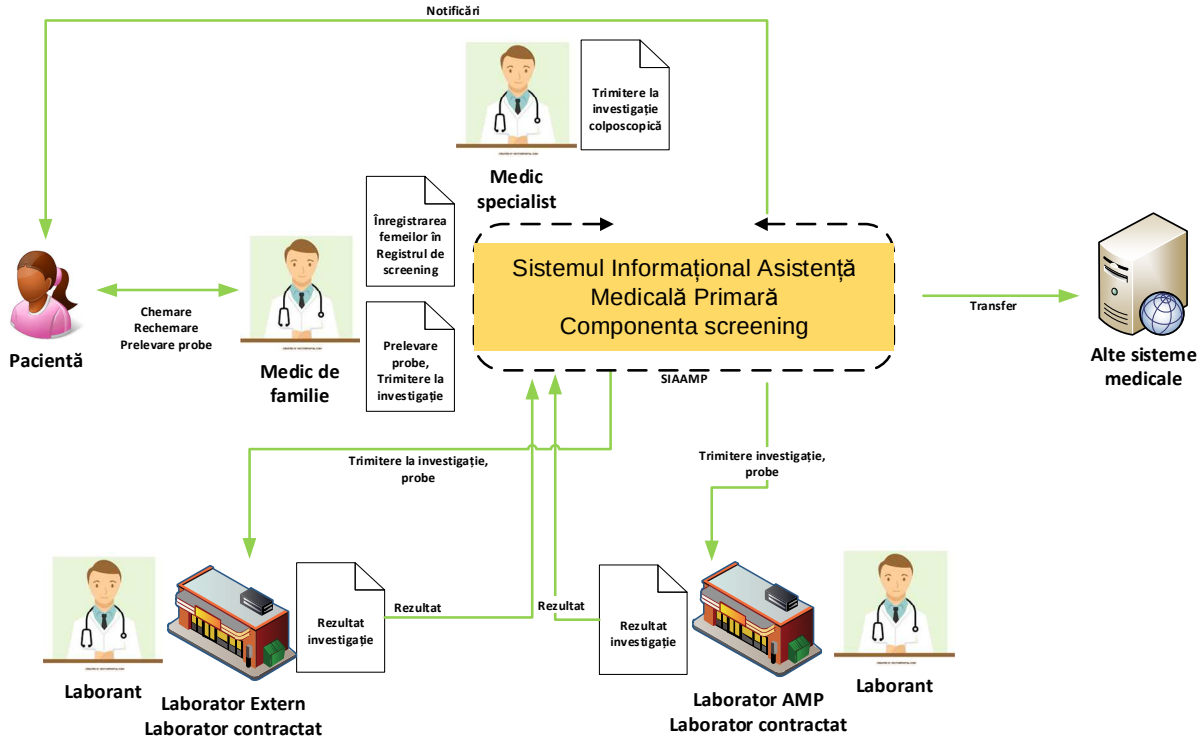


Figure 1 – Diagram of Cervical Screening Registry flows

Data will be entered into the Cervical Screening Registry in line with the requirements set in the instruction developed by MoHLSP and approved by a Government Decision.

General requirements for the development of SIA AMP, transfer of knowledge and consultancy

Security and audit requirements

To develop the system, the developer will comply with the requirements set out in the Government Decision No 1123 of 14 December 2010 approving the Requirements for ensuring the security of personal data during their processing in the information system of personal data, Official Gazette No 254-256 of 24 December 2010, minimum:

1. Authentication in the system shall be done by using the Government authentication and control service of the MPass access;
2. Possibility to identify and authenticate the equipment used to process the personal data;
3. The administration of user identifiers shall include:
   1) univocal identification of each user;
   2) checking the authenticity of each user;
   3) obtaining the authorization from the person responsible for issuing the user ID;
   4) ensuring that the user ID is issued to a person that was correctly determined;
   5) deactivating the user account after an inactive period, established in advance (inaction for a maximum period of 2 months);
   6) making archive copies of user IDs.
4. The user's attempts to log in/log out the system shall be recorded according to the following parameters:
   1) the date and time of the log in/log out attempt;
   2) User ID;
   3) the result of the log in/log out attempt – positive or negative.
5. The attempts to start/end the working session of the applicative programs and processes intended for processing personal data, changes to users' access rights, and the status of the access objects shall be recorded according to the following parameters:
   1) date and time of the start attempt;
   2) name/identifier of the applicative program or process;
   3) User ID;
   4) outcome of the start attempt – negative or positive.
6. The attempts to obtain access (execution of operations) for applications and processes intended for personal data processing shall be recorded according to the following parameters:
   1) date and time of the attempt to obtain the access (execution of operation);
   2) name (identifier) of the application or process;
   3) User ID;
   4) specifications of the protected resource (identifier, logic name, file name, number, etc.);
   5) type of the operation requested (read, record, delete, etc.);
   6) outcome of the attempt to obtain the access (execution of operation) – negative or positive.
7. Changes to user's access rights (competences) and the status of access objects shall be recorded according to the following parameters:
   1) date and time when competences are changed;

2) ID of the administrator who made the changes;
3) user ID and his/her competencies or specifying the access objects and their new status.

8. The retrieval of personal data information from the system (electronic documents, data, etc.), changes to subjects' access rights and the status of access objects shall be recorded according to the following parameters:
   1) date and time of the retrieval;
   2) name of the information and the ways to access it;
   3) specification of the equipment (device) that released the information (logical name);
   4) user ID of the person who requested the information;
   5) volume of the document retrieved (number of pages, tabs, copies) and the result of the retrieval – positive or negative.
9. The results of the security audit shall be stored for no less than two years with the possibility to extend this term if necessary (investigations or legal proceedings).
10. Cervical Screening Registry will be integrated with the governmental electronic journaling service MLog, having as objective the evidence, journaling and audit of events in the system, in accordance with p. 4 of Government Decision 708/2014. Business processes subject to the MLog journaling mechanism:
    - Access/modify/create the patient's medical record
    - Request for paraclinical investigation
    - Validation of paraclinical investigation result
    - View the paraclinical investigation result
    - View the reports
11. Cervical Screening Registry will be integrated with the governmental electronic notification service MNotify. MNotify service will allow notification of recipients through different notification channels (electronic address (e-mail), short message service (SMS), instant messenger (chat), push notifications and the Government for Citizen Portal).

Service Quality Requirements

Working model. Intervention procedures

The system is hosted in the Government Cloud and operates on a professional basis. Access to the system's servers is done securely both inside and outside the data center. When performing maintenance work, it is important to maintain proper communication between the Provider's team and the Beneficiary's team. The Beneficiary's experts must understand the technical terminology specific to the information systems, not only the terminology specific to the application. The Beneficiary's previous experience has shown that some situations can be dealt with only when technical groups from all the system's levels are involved, provided that the quality and safety of the system is maintained constantly.

Good communication among support teams is essential in the process of expanding the system and providing a good user experience. All such operations are carried out in conditions of maximum cybersecurity, with strict observance of the law in force.

The extension of software platform at the application level is carried out securely by experts accessing it outside the data center. Simpler situations, especially recommendations, can be handled by phone or e-mail. However, situations with a higher complexity or risk may arise, which require mandatory on-site presence of the technical support teams and communication between their managers for the operations to be successful. In case of incidents, the Provider shall ensure the following intervention procedures during the contract period:

- Secure remote intervention [remote access]. The recommendations of the specialists of the Governmental Cloud Data Center will be followed;
- Technical interventions and recommendations by telephone, by email, or by other means of electronic communication, including video conferencing;
- On-site interventions, in situations when the specialists of the Government Data Center consider necessary such an approach to the situation.

Intervention time [SLA]

The system is designed for a correct and continuous functioning. The scheduled interventions and their duration are agreed with the Beneficiary following the consultation and approval by all support departments. The internal services for this project are created to ensure a level of availability to which the services purchased through this procedure must be aligned. In case of an incident, required time for technical operations is the following:

Response time	2 hours
Intervention time for server malfunctions or alteration of system configuration in the Government Cloud, as well as major system components. Note: if needed, the request can be for on-site intervention.	2 hours
Intervention time for corrective actions	8 hours

Annex 1

Reports (automatically created by the system, also available in EXCEL format)

Reports for Primary Health Care

1. The total list of women eligible for screening in the current year/required period:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor);
   - Surname, name;
   - Age;
   - Result of the previous test;
   - Year of the previous test;
   - Result of the penultimate test;
   - Year of the penultimate test.
2. The total list of outstanding women, who were not screened during the past two years/required period:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor);
   - Surname, name;
   - Age;
   - Result of the previous test;
   - Year of the previous test;
3. The total list of women, who were screened in the current year/required period and were found to have a NILM result
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor);
   - Surname, name;
   - Age;
   - Result of the previous test;
   - Year of the previous test;
   - Result of the penultimate test;
   - Year of the penultimate test;
   - Recommendations from the cytological result form.
4. The total list of women that were screened in the current year/required period and were found to have an atypical result (ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions)
   - No in the queue;
   - ID;

- No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor);
- Surname, name;
- Age;
- Result of the previous test;
- Year of the previous test;
- Result of the penultimate test;
- Year of the penultimate test;
- Recommendations from the cytological result form.

5. The total list of women that were screened in the current year/required period and were found to have an UNSAT result
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor);
   - Surname, name;
   - Age;
   - Result of the previous test;
   - Year of the previous test;
   - Result of the penultimate test;
   - Year of the penultimate test;
   - Recommendations from the cytological result form.
6. Rate of screening coverage in the current year/required period (available per doctor/institution/district/country):
   - It will be calculated as a percentage of the total number of women that received the cytological result, which was viewed by the family doctor to the total number of women eligible for screening;
7. Rate of recruitment for screening in the current year/required period (available per doctor/institution/district/country):
   - It will be calculated as a percentage of the total number of women that received the cytological result to the number of women invited for screening (* the invitation will be active at the moment of printing the invitation letter)
8. Rate of women that were found to have atypical result in the current year/required period (available per doctor/institution/district/country):
   - It will be calculated as a percentage of the total number of women with atypical result (ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) to the total number of women that received the cytological result
9. Rate of women that were found to have high level atypicalities in the current year/required period (available per doctor/institution/district/country):
   - It will be calculated as a percentage of the total number of women with atypical result (ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) to the total number of women that received the cytological result
10. The total list of women referred for colposcopy in the current year/required period (per doctor/institution/district/country)

- No in the queue;
- ID;
- No of PHC outpatient file (* the active box that allows accessing the PHC record/colposcopy to view more details about the patient's history and family doctor, coploscopist, and accessing the laboratory file to view the investigations history);
- Surname, name;
- Age;
- Current cytological result;
- Recommendations from the cytological result form
- Result of the previous test;
- Year of the previous test;
- Result of the penultimate test;
- Year of the penultimate test;
- Previous colposcopies (yes/no);
- Previous colposcopic treatment (yes/no)

11. The total list of colposcopically examined women in the current year/required period (per doctor/institution/district/country)
    - No in the queue;
    - ID;
    - No of PHC outpatient file (* the active box that allows accessing the PHC record/colposcopy to view more details about the patient's history and family doctor, coploscopist, and accessing the laboratory file to view the investigations history);
    - Surname, name;
    - Age;
    - Current cytological result;
    - Recommendations from the cytological result form
    - Result of the previous test;
    - Year of the previous test;
    - Result of the penultimate test;
    - Year of the penultimate test;
    - Previous colposcopies (yes/no);
    - Previous colposcopic treatment (yes/no).
12. Rate of women referred for colposcopy in the current year/required period (per doctor/institution/district/country)
    - It will be calculated as a percentage of the total number of women that received a recommendation for colposcopy according to the 'Cervical cytological investigation result – 203-2/e' form to the total number of women invited/referred for colposcopy (* the reference will be active at the moment of printing the invitation letter)
13. Rate of women colposcopically examined in the current year/required period (per doctor/institution/district/country)
    - It will be calculated as a percentage of the total number of women colposcopically examined to the total number of women invited/referred for colposcopy (* the reference will be active at the moment of printing the invitation letter)

14. Rate of women referred for colposcopy and examined in due time according to the Algorithm of Cytology Results Management in the current year/required period (per doctor/institution/district/country)
    - It will be calculated as a percentage of the total number of women referred for colposcopy and examined in due time according to the Algorithm to the number of women eligible for colposcopy according to the Algorithm and/or recommendation from 'Cervical cytological investigation result – 203-2/e'
15. Rate of women with UNSAT in the current year/required period (available per doctor/institution/district/country):
    - It will be calculated as a percentage of the total number of women with UNSAT to the total number of cytology results produced
16. Rate of eligible age women screened in the current year/required period (available per doctor/institution/district/country):
    - It will be calculated as a percentage of the total number of screened women of eligible age to the total number of screened women
17. Rate of screened women during recommended interval in the current year/required period (available for doctor/institution/district/country):
    - It will be calculated as a percentage of the total number of screened women with an interval of 3 years + the total number of screened women within the recommended interval in the 'Cervical cytological investigation result – 203-2/e' and 'Result of colposcopic examination – 232/e-1' forms to the total number of screened women.

Reports for Cytology Laboratory

1. The list of cytologies Registryed in laboratory in the current year/required period (per laboratory/country)
    - No in the queue;
    - ID;
    - Surname, name;
    - Age;
    - PHCF of PHC;
    - Date of cytology collection;
    - Date of registration in the laboratory.
2. Rate of investigations Registryed in the laboratory within 7 days from collection in the current year/required period (per laboratory/country):
    - It will be calculated as a percentage of the total number of cytology tests Registryed in the laboratory within 7 days from the collection date to the total number of cytology tests Registryed in the laboratory
3. Rate of 'Cervical cytology request form – 203-1e' forms appropriately filled in the current year/required period (per laboratory/country):
    - It will be calculated as a percentage of the total number of forms appropriately filled in to the total number of forms Registryed in the laboratory
4. Rate of damaged slides in the current year/required period (per laboratory/country/PHCF of PHC):

- It will be calculated as a percentage of the total number of samples not Registryed due to incorrect transportation or damage to the total number of collected slides

5. The list of Registryed NILM cytology in the current year/required period (per laboratory/country):
   - No in the queue;
   - ID;
   - Surname, name;
   - Age;
   - PHCF of PHC;
   - Date of registration in laboratory;
   - Date of primary examination;
   - Result of primary examination;
   - Date of swift examination;
   - Result of swift examination;
   - Date of examination by doctor;
   - Result of examination by doctor;
   - Date of the final result;
   - Final result;
   - Recommendation.
6. Rate of NILM results examined by doctor in the current year/required period (per laboratory/country)
   - It will be calculated as a percentage of the total number of NILM results examined by doctor to the total number of NILM results
7. List of UNSAT cytology results in the current year/required period (per laboratory/country)
   - No in the queue;
   - ID;
   - Surname, name;
   - Age;
   - PHCF of PHC;
   - Date of registration in laboratory;
   - Date of primary examination;
   - Result of primary examination;
   - Date of swift examination;
   - Result of swift examination;
   - Date of examination by doctor;
   - Result of examination by doctor;
   - Date of the final result;
   - Final result;
   - Recommendation.
8. Rate of UNSAT cytology results in the current year/required period (per laboratory/country)
   - It will be calculated as a percentage of the total number of UNSAT cytology results to the total number of cytology results produced by laboratory

7.,8.,9.,10.,11.,12.,13.,14.,15.,16.,17. The lists of atypical cytology results (ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) in the current year/required period (per laboratory/country)

- No in the queue;
- ID;
- Surname, name;
- Age;
- PHCF of PHC;
- Date of registration in laboratory;
- Date of primary examination;
- Result of primary examination;
- Date of swift examination;
- Result of swift examination;
- Date of examination by doctor;
- Result of examination by doctor;
- Date of the final result;
- Final result;
- Recommendation.

18.,19.,20.,21.,22.,23.,24.,25.,26.,27.,28. Rate of abnormalities detected in the current year/required period (per laboratory/country)

- It will be calculated as a percentage of the total number of atypical cytology results to the total number of cytology results produced by laboratory.

29.,30.,31.,32.,33.,34.,35.,36.,37.,38.,39. The structure of atypical cytology results (ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) of the total number of abnormalities detected in the current year/required period (per laboratory/country)

- It will be calculated as a percentage of every atypical result from the number of abnormalities to the total number of abnormalities detected by laboratory

40. The list of investigations per health worker (laboratory technician, doctor) in the current year/required period (per laboratory/country):

- No in the queue;
- Surname, name of the health worker;
- ID of the examined cytology sample (* the active box, that allows accessing all data about this case from laboratory and/or per program);
- date of the primary examination;
- result of the primary examination;
- date of the swift examination;
- result of swift examination;
- date of examination by doctor;
- result of examination by doctor;

- date of conclusion;
- result of conclusion.

41. The list of cytology results produced in more than 30 calendar days in the current year/required period (per laboratory/country):

- No in the queue;
- The ID of examined cytology sample (* the active box that allows accessing all data about this case from laboratory and/or per program);
- date of the primary examination;
- result of the primary examination;
- date of the swift examination;
- result of swift examination;
- date of examination by doctor;
- result of examination by doctor;
- date of conclusion;
- result of conclusion.

42. Rate of cytology results produced in more than 30 calendar days in the current year/required period (per laboratory/country):

- it will be calculated as a percentage of the total number of atypical cytology results produced in more than 30 days to the total number of cytology results produced by laboratory.

Colposcopy Reports

1. Total list of women referred for colposcopy (source SIA SR of PHC when filling in the Referral to Colposcopic Examination – 232/e form by the family doctor) in the current year/required period, is also found in the reports from PHC, point 10, by PHCF of PHC, PHC sector, colposcopy office:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, accessing the laboratory file to view the investigations history);
   - Surname, name;
   - Age;
   - Cytology test result that caused the referral for colposcopy;
   - Date of cytology test that caused the referral for colposcopy;
   - Recommendations from the form with the cytological result;
   - Date of referral to colposcopy;
   - The colposcopy office where the patient was referred;
   - Result of the previous test;
   - Date of previous test;
   - Previous colposcopies (yes/no);
   - Previous colposcopic treatment (yes/no).

2. Total list of women with outstanding colposcopy tests, referred according to the Referral to Colposcopic Examination – 232/e form, but did not made the colposcopy in the current year/required period, by PHCF of PHC, PHC sector, colposcopy office:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
   - Surname, name;
   - Age;
   - Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)
   - The colposcopy office where the patient was referred.
3. Total list of women referred for colposcopy and examined, but who came for colposcopy with delay of ≤ 2 weeks, ≤ 12 weeks, > 12 weeks compared with predefined referral terms set out by the Algorithm of Cytology Results Management, in the current year/required period, by PHCF of the PHC, PHC sector, the colposcopy office:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
   - Surname, name;
   - Age;
   - Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)
   - Colposcopy office where the patient was referred;
   - Colposcopy result;
   - Recommendations.
4. Total list of women referred for colposcopy and examined within the referral terms set out in the Algorithm of Cytology Results Management, classified by atypical reference indication (ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions), in the current year/required period, by PHCF of PHC, PHC sector, colposcopy office:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
   - Surname, name;
   - Age;
   - Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)

- Colposcopy office where the patient was referred;
- Colposcopy result;
- Recommendations.

5., 6. List of women subject to primary/secondary colposcopic examination (total, insured, uninsured) classified by ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions:

- No in the queue;
- ID;
- No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
- Surname, name;
- Age;
- Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)
- Colposcopy office where the patient was referred;
- Colposcopy result;
- Recommendations.

7. List of women colposcopically examined (primary/secundary), (insured/uninsured), from whom biopsy was taken, classified by ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions:
   - No in the queue;
   - ID;
   - No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
   - Surname, name;
   - Age;
   - Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)
   - Colposcopy office where the patient was referred;
   - Colposcopy result;
   - Biopsy result;
   - Recommendations.
8. List of women (primary/secundary), (insured/uninsured), who received excisional colposcopy treatment, classified by ASC-US, LSIL, ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions:
   - No in the queue;
   - ID;

- No of PHC outpatient file (* the active box that allows accessing the PHC record to view more details about the patient's history and family doctor, and accessing the laboratory file to view the investigations history);
- Surname, name;
- Age;
- Date of colposcopy referral (* the active box that allows accessing directly the Referral to Colposcopic Examination – 232/e form)
- Colposcopy office where the patient was examined;
- Date of the colposcopy examination;
- Colposcopy result;
- Biopsy taken (yes/no)
- Biopsy result (waiting, result)
- Colposcopy treatment (yes: treatment type: LEEP, LLETZ, HET)
- - Histology result after treatment, extract from point 12: data on the information item (Result of histopathological investigation in single or multifocal cervical biopsies/excisions – 234-1/e)
- Recommendations.

9. Total number of visits to colposcopy:

- insured/uninsured/paid;
- primary/secondary;
- monitoring/post-treatement;
- with reference/consultation;
- Pregnant women during I/II/III trimester

10. Rate of women referred according to the Referral to Colposcopic Examination – 232/e and colposcopically examined in due time according to the Algorithm of Cytology Results Management, in the current year/required period (per doctor/institution/country)
    - It will be calculated as a percentage of the total number of women referred according to the Reference for Colposcopic Examination – 232/e and colposcopically examined in due time according to the Algorithm to the total number of colposcopically examined women.
11. Rate of women colposcopically examined without the Referral to Colposcopic Examination – 232/e in the current year/required period (per doctor/institution/country):
    - It will be calculated as a percentage of the total number of women colposcopically examined without the Reference for Colposcopic Examination – 232/e to the total number of colposcopy examinations.
12. Rate of women with severe atypicalities (ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) colposcopically examined in the current year/required period (per doctor/institution/country):
    - It will be calculated as a percentage from the total number of women with ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions colposcopically

examined to the total number of women with the mentioned atypicality, who received the Reference for Colposcopic Examination – 232/e

13. Rate of women with severe atypicalities (ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions) colposcopically examined in the current year/required period (per doctor/institution/country) in the structure of colposcopy examinations:
    - It will be calculated as a percentage from the total number of women with ASC-H, HSIL, HSIL with suspected invasion, SCC, endocervical AGC, AGC FN, AGC-NOS, AGC FN with suspected invasion, other malignant lesions colposcopically examined to the total number of colposcopically examined women.
14. Rate of women with a SWEDE Score ≥5 from whom biopsy was taken in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of women with a SWEDE Score ≥5 from whom biopsy was taken to the total number of women with a WEDE Score ≥5 colposcopically examined
15. Rate of women with a SWEDE Score ≥5 from whom biopsy was taken in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of women with a SWEDE Score ≥5 from whom biopsy was taken at the first consultation to the total number of women with a SWEDE Score ≥5 from whom biopsy was taken
16. Rate of women with a SWEDE Score <5 from whom biopsy was taken in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of women with a SWEDE Score <5 from whom biopsy was taken to the total number of women with a WEDE Score <5 colposcopically examined.
17. Rate of CIN 2+ results in the structure of biopsies performed this year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of examined CIN II+ to the total number of biopsies performed by the colposcopy office.
18. Rate of colposcopically examined women without the Referral to Colposcopic Examination – 232/e from whom biopsy was taken in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of colposcopically examined women without the Reference for Colposcopic Examination – 232/e from whom biopsy was taken to the total number of colposcopy examinated women without the Reference for Colposcopic Examination – 232/e.
19. Correlation table of the referral cytological results/Swede score/biopsy/excisional post-treatment histology in the current year/during the required period (per doctor/institution/country):
    - No in the queue;
    - ID;
    - Surname, name;
    - Age;
    - Laboratory/cytologist who performed the cytology;
    - Cytological result;

- Colposcopy office/doctor who performed the colposcopy;
- SWEDE score;
- Colposcopy office/doctor who performed the biopsy;
- Biopsy result (waiting, result);
- Colposcopy office/doctor who performed the colposcopy treatment (yes: type of treatment: LEEP, LLETZ, HET);
- Post-treatment histology result

20. Rate of women with a SWEDE Score ≥5 for whom biopsy/LLETZ was made with CIN 2+ result in the current year/required period (per doctor/institution/country)
    - it will be calculated as a percentage of the total number of CIN 2+ biopsies with a SWEDE Score ≥5 to the total number of biopsies of women with a SWEDE Score ≥5
21. Rate of CIN 2+ results among biopsy results who received excisional treatment in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of women with CIN 2+ who received excisional treatment to the total number of excisional treatments
22. Rate of CIN 2+ results after excisional treatments in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of examined CIN 2+ results in the post-excisional histology to the total number of excisional treatments
23. Rate of appropriate histology results after excisional treatment in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of appropriate histology results (positive excisional margins, the quality of sample, denuded margins, the thickness of the sample, etc. from the Result of the investigation in cervical excisional biopsies – 234-1/e form) to the total number of excisional treatments.
24. Rate of LEEP/LLETZ excisions at the first visit in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of LEEP/LLETZ excisions performed at first consultation for colposcopy to the total number of excisional treatments performed
25. Rate of inappropriate excisions at women ≥ 50 years in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of inappropriate excisions at women ≥ 50 years to the total number of inappropriate excisions
26. Rate of biopsies performed through excisions in TZ type 3 in the current year/required period (per doctor/institution/country):
    - it will be calculated as a percentage of the total number of biopsies performed through excisions at women with TZ type 3 to the total number of women with TZ 3
27. Rate of pregnant women referred for colposcopy with SWEDE Score ≥5 from whom biopsy was taken in the current year/required period (per doctor/institution/country);
28. Rate of pregnant women from whom biopsy was taken during the pregnancy with CIN 2+ result in the current year/required period (per doctor/institution/country);

29. Rate of pregnant women from whom biopsy was taken during the pregnancy with CIN 2+ result, who received postpartum excisional treatment in the current year/required period (per doctor/institution/country).

Histological Reports

1. List of biopsies/excisional material recorded in the laboratory in the current year/required period (per laboratory/country/PHCF colposcopy office)
   - No in the queue;
   - ID;
   - Surname, name;
   - Age;
   - PHCF which referred the sample;
   - Date of biopsy/histology collection;
   - Date of registration in the laboratory.
2. Rate of laboratory investigations Registryed within 48 hours after collection in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - It will be calculated as a percentage of the total number of samples Registryed in the laboratory within 48 hours from the date of collection to the total number of samples Registryed in the laboratory
3. Rate of 'Referral to histopathological investigation in single or multifocal cervical biopsies/excisions – 234/e' forms appropriately filled in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - It will be calculated as a percentage of the total number of forms appropriately filled in to the total number of forms Registryed in the laboratory
4. Rate of 'Referral to histopathological investigation of the post-surgery material after hysterectomy – 233/e' forms appropriately filled in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - It will be calculated as a percentage of the total number of forms appropriately filled in to the total number of forms Registryed in the laboratory
5. Rate of damaged samples in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - It will be calculated as a percentage of the total number of unRegistryed samples because of incorrect transportation or damage to the total number of collected samples
6. Rate of samples transported in solution of 10% formalin in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - It will be calculated as a percentage of the total number of samples transported in solution of 10% Formalin to the total number of transported samples
7. The list of CIN 2- results from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - No in the queue;
   - ID;
   - Surname, name;
   - Age;

- PHCF colposcopy office;
- Cytological result;
- SWEDE score;
- Colposcopy conclusion
- Date of registration in laboratory;
- Date of the final result;
- Final result;
- Recommendation.

8. Rate of CIN 2- results from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country/PHCF colposcopy office)
   - It will be calculated as a percentage of the total number of examined CIN 2 results to the total number of hystology results

9. The list of CIN 2+ results (classified under CIN 2, CIN 3, CIS, CIN 3 with invasion, microinvasive squamous cancer, CGIN, adenocarcinoma) from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country/PHCF colposcopy office):
   - No in the queue;
   - ID;
   - Surname, name;
   - Age;
   - PHCF colposcopy office;
   - Cytological result;
   - SWEDE score;
   - Colposcopy conclusion
   - Date of registration in laboratory;
   - Date of the final result;
   - Final result;
   - Recommendation.
10. Rate of CIN 2+ results from biopsies/excisional samples/post-surgery material after hysterectomy (classified under CIN 2, CIN 3, CIS, CIN 3 with invasion, microinvasive squamous cancer, CGIN, adenocarcinoma) examined in the current year/required period (per laboratory/country/PHCF colposcopy office)
    - It will be calculated as a percentage of the total number of CIN 2+ examined results of each type, to the total number of hystological results
11. The list of unclassified SIL results from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country)
    - No in the queue;
    - ID;
    - Surname, name;
    - Age;
    - PHCF colposcopy office;

- Cytological result;
- SWEDE score;
- Colposcopy conclusion
- Date of registration in laboratory;
- Date of the final result;
- Final result;
- Recommendation.

12. Rate of unclassified SIL results from biopsies/excisional samples/post-surgery material after hysterectomy examined in the current year/requested period (per laboratory/PHCF colposcopy office)
    - It will be calculated as a percentage of the total number of unclassified SIL results to the total number of results produced by laboratory

13. The list of invalid results for the processing of the results from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country/PHCF colposcopy office)
    - No in the queue;
    - ID;
    - Surname, name;
    - Age;
    - PHCF colposcopy office;
    - Cytological result;
    - SWEDE score;
    - Colposcopy conclusion
    - Date of registration in laboratory;
    - Date of the final result;
    - Final result;
    - Recommendation.
14. Rate of invalid results for the processing of the result from biopsies/excisional samples/post-surgery material after hysterectomy in the current year/required period (per laboratory/country/PHCF colposcopy office)
    - It will be calculated as a percentage of the total number of invalid results to the total number of results produced by laboratory
15. Rate of results from biopsies/excisional samples/post-surgery material after hysterectomy examined in 7 days/14 days/30 days in the current year/requested period (per laboratory/PHCF colposcopy office)
    - It will be calculated as a percentage of the total number of results produced in 7 days/14 days/30 days to the total number of the results produced
16. List of investigations results from biopsies/excision samples/post-surgery material after hysterectomy per diagnosis developed (CIN 1, CIN 2, CIN 3, CIN 3 with invasion per health worker (laboratory technician, doctor), microinvasive squamous cancer, invasive squamous cancer, GCIN, Adenocarcinoma, invalid samples, unclassified SIL, etc.) in the current year/required period (per laboratory/country):

- No in the queue;
- ID;
- Surname, name;
- Age;
- PHCF colposcopy office;
- Cytological result;
- SWEDE score;
- Colposcopy conclusion
- Date of registration in laboratory;
- Date of the final result;
- Final result;
- Recommendation.

17. The structure of hystological results produced from biopsies/excision samples/post-surgery material after hysterectomy per diagnosis (CIN 1, CIN 2, CIN 3, CIN 3 with invasion, microinvasive squamous cancer, invasive squamous cancer, GCIN, Adenocarcinoma, invalid samples, unclassified SIL, etc.) per health worker (laboratory technician, doctor) in the current year/required period (per laboratory/country):
    - It will be calculated as a percentage of the total number of each separate result produced by doctor/laboratory technician to the total cytological results produced by health worker/laboratory.
18. Correlation table of the reference cytological results/biopsy/excisional post-treatment histology/post-surgery material after hysterectomy in the current year/during the required period (per doctor/institution/country/PHCF colposcopy office):
    - No in the queue;
    - ID;
    - Surname, name;
    - Age;
    - Laboratory/cytologist who performed the cytology;
    - Cytological result;
    - Colposcopy office/doctor who performed the colposcopy;
    - SWEDE score;
    - Colposcopy office/doctor who performed the biopsy;
    - Biopsy result (waiting, result);
    - Colposcopy office/doctor who performed the colposcopy treatment (yes: type of treatment: LEEP, LLETZ, HET);
    - Post-treatment histology result

Annex 2

Management depending on the cytological result

Bethesda Classification	Interpretation of Cytology	Management
NILM	Negative for intraepithelial lesion or malignancy Adequate Pap test without recording abnormal cells	Routine recall every 3 years;
	Special cases:	
	a. HIV positive women	Annual recall at the age of 20
	b. 1st Pap test after a previous ASC-US or LSIL result, or after the treatment of a low-grade abnormality. In order to return to routine recalls, 2 NILM Pap tests are required	Repeat at 6 months
	c. 1st Pap test after an AGC result or after the treatment of a low-grade abnormality.	Repeat at 6 and 12 months and then annually for 4 years (5-year monitoring in total)
	d. 1st Pap test after a HSIL result or AGC-FN, or treatment.	Repeat at 6 and 12 months and then annually for 9 years (10-year monitoring in total)
	e. Suspicious cervix.	Colposcopic referral within 14 days.
UNSAT	Unsatisfactory	Repeat Pap test in 3 months
	a. The sampler states that the cervix was poorly viewed	Repeat after 3 months or refer to gynecologist
	b. The third inadequate/unsatisfactory Pap test.	Colposcopic referral within 28 days
ASC-US	Atypical Squamous Cells of Uncertain Significance	Repeat Pap test after 6 months
	Special cases:	
	a. 1st Pap test with ASC-US after a CIN treatment	Colposcopic referral within 28 days
	b. The second consecutively Pap test with ASC-US	
	c. Any third abnormal Pap test during the last 10 years.	
	d. 1st ASC-US for HIV positive women.	
LSIL	Low Grade Squamous Intraepithelial Lesion	Repeat Pap test after 6 months
	Special cases:	
	a. 1st LSIL after a treatment for CIN	Colposcopic referral within 28 days
	b. The second consecutive LSIL result	
	c. Any third abnormal Pap test during the last 10 years	
	d. 1st LSIL for HIV positive women	

Bethesda Classification	Interpretation of Cytology	Management
ASC-H	Atypical squamous cells do not exclude HSIL	Colposcopic referral within 14 days
HSIL	High Grade Squamous Intraepithelial Lesion a. High Grade Squamous Intraepithelial Lesion with Suspected Invasion	Colposcopic referral within 14 days
AGC	Atypical Glandular Cells • Endocervical • Unspecified otherwise (NOS) • Non-specific type	Colposcopic referral within 14 days
AGC, FN	Atypical Glandular Cells, suggestive modifications for neoplasia • Endocervical • Endometrial • Unspecified otherwise (NOS) • Non-specific type with suspected invasion (Adenocarcinoma)	Colposcopic referral within 14 days
SCC	Squamous cells carcinoma with cytological signs associated with invasive malignancy *and* suggestive clinical details, as visually suspicious cervix, the presence of symptoms, etc.	Referral to gynecologic oncologist/Oncological Institute within 7 days
Other malignant lesions		Referral to gynecologic oncologist/Oncological Institute within 7 days