**TERMS OF REFERENCE**

**Development of the Laboratory Information System (LIS) for the public health laboratory network with regards to communicable diseases, including COVID-19 laboratory testing**

*1 April – 30 September 2021*

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| 1. **Background** |
| The Minister of Health, Labor and Social Protection (MoHLSP), through the National Agency for Public Health (NAPH), based on the Government Decision[[1]](#footnote-1) is responsible for maintaining, managing and improving the national surveillance and control system for communicable diseases and public health events. The laboratory confirmation is an important component of the roll-out the surveillance of the communicable diseases one of the important components of the surveillance.  The laboratory confirmation of COVID-19 cases is an important pillar of the National Emergency Preparedness and Response plan[[2]](#footnote-2) approved by the National Extraordinary Committee for Public Health, which was developed based on the WHO Strategic Preparedness and Response for COVID-19. The COVID-19 testing is conducted in the national reference laboratory for virology, at the National Agency of Public Health and regional public health laboratories. The number of laboratories included in the process of SARS-CoV-2 detection was slowly increased.  In Dec 2020 a comprehensive in country COVID-19 Intra-Action Review (IAR) was conducted with WHO support and laboratory service and capacities were evaluated. The assessment allowed to identify strengthens and weaknesses as well as action points to strengthening the laboratory capacities. The Laboratory Information system (LIS) needs to be developed and implemented in all public health labs. All laboratories are reporting their results on a daily basis to the regional and National Agency of Public Health.  The laboratory work in the national and regional public health laboratories is well organized and the standard operational procedures (SOP) are followed by the laboratory staff however, the data is handling manually. The samples data processing and increasing number of samples require additional human resources involved in the registration and laboratory processing. Thus, information about patients have to transfer in the lab logbook and after the investigation the information have to be fulfilled in the standard template. There is no an automatic link between samples and digital equipment which process samples and results are transcript. One of the solution to optimize data flow in the laboratory rely on development of the IT solution, which is define as a laboratory information (management) system (LIS).  Implementation of LIS should address the needs of all three analytical phases and ensure: minimizing number of errors when performing laboratory investigations (mainly related to the patient's identity), as well as cases of loss of data and related replication studies; ensuring security and confidentiality requirements when using information systems; improving functionality and capability such as registration of patients and their samples received for analysis, with possibility of manual registration and entering the data by the operator, automatically retrieving data from other information systems, as well as specialized readers; registration of laboratory investigation tasks for each sample and distribution of sample tasks between laboratory workplaces, receiving from another information system (IS) or from a specialized readers and transmission the data to automatic aliquoting; registration of laboratory investigation results, automatic receiving of data from analyzers, as well as entering the results manually; providing the answer-forms with research results with the possibility of sorting the printed reports, indicating the research results, the limits of the norm of each indicator in accordance with the normative group of the patient and deviation of the indicator from the norm to facilitate the interpretation of the results; conducting quality control statistics of laboratory allowing the receiving the results of test measurements directly from the analyzer, conforming the quality control methodology with existing regulatory framework; ability to track the lab investigation process by the senior staff; automatic creation of various reports, a set of standard reports, individual reports, preferably using the report generation module, that allows the user to independently develop the required reporting forms, including different types of analyses, different time frames, comparison of different data depending of the end user needs etc.; archiving in a format that guarantees the continuity of data over a long period of time, tracking technological developments such as changes in reagents and changes in indicator standards.  The laboratory quality management is a comprehensive system and require automatization of the processes in conducting quality control statistics of laboratory. Data exchange and interoperability with other electronic system is another important component which will allow to avoid work duplication and reduce the errors.  So, LIS (electronic platform) for the public health laboratory network, with development of the associated documents have been required by the Ministry of Health, Labour and Social Protection in the official letter nr.04/7375 from 29.12.2020.  Thus, WHO Country Office of Moldova in the context of strengthening the National laboratory capacities as part of the surveillance system for communicable diseases, including for COVID-19, is looking to recruit an IT company to develop the LIS functionalities in line with the concept note and technical specifications. The selected IT company will work in close collaboration with representatives of NAPH and MoHLSP and WHO consultants and staff. |
| 1. **Deliverables** |
| **Overall objective:** to propose a solution to implement Laboratory Information System (LIS) for the public health laboratory network with regards to the communicable diseases laboratory investigations, including COVID-19 laboratory testing and solution for data exchange with other electronic information systems in the health area.  **Specific Objectives**  The specific objectives of the work will be as follows:   1. To propose and implement the IT solution (LIS) for 25 Automated workplaces providing the necessary amount of licenses; 2. To install software components, set up program interface and train personnel directly involved in working with the implemented system, liaising with collaborators such as laboratory staff, data managers, statisticians, data entry and data analysis experts within the NAPH to optimize processes for development of the new system and to ensure participation in working meeting (face-to-face/online), as needed; 3. To ensure technical support and troubleshooting during implementation stage and within a time defined in the contract as a maintenance period; 4. To ensure information security and data protection within the system, also accomplishments of requirements related to protection of personal data.   **Deliverables:**  1. Presentation, development and installation of the IT solution of the Laboratory Information System:   * Laboratory Information System. Automated workplace, 25 working stations; * Laboratory Information System. Laboratory analyzer driver; * Laboratory Information System. Integrated Standard data interface module for uploading information to the External Systems; * Non-exclusive right to use software: Laboratory Information System. Integrated Standard Data interface module for downloading information from the external system.   2. Configuration of the LIS software platform:   * Configuring software package ‘Laboratory Information System’ and server (if needed); * Adjustment of license (if necessary); * Configuring other licenses and client access licenses (if necessary).   3. Working on LIS configuring in Laboratories (national and 10 regional) of the National Agency for Public Health:   * LIS configuration and deployment works; * Adjustment of the program interface (should be in national language).  1. LIS System testing:  * Elaboration of testing scenarios for system functionality conducting testing works; * Testing results reports (system proper operability).   5. Comprehensive maintenance of LIS:   * Comprehensive maintenance of the LIS within the period of one year immediately following the LIS launching.   6. Progress reports are developed and presented, with overall status on the project development and implementation (one report per month, including final report).  7. Conducting trainings (in national language) for Laboratory staff on how to operate the LIS and for IT-specialists on system administration, through the implementation period and before commissioning of the system.  8. Development of User manuals and reference documentation (in national language);  9. Granting the guarantee minimum for 12 months from the date of signing the final acceptance;  **Remark**  The beneficiary reserves the right to make changes in volume of 10% from amount of work described in the technical specification. |
| 1. **Contract duration** |
| The duration of Contract *1 April – 30 September 2021*  **Payment schedule**   * 25% as instalment I – upon signing of contract agreement * 75% last instalment– upon successful completion of work and submission of financial, technical reports, testing report and Application Codes |
| 1. **Qualifications, experience, skills and languages** |
| **Skills and Qualifications**  The Service Provider should have knowledge and experience in the following areas:   * Having a working knowledge of common information technologies and systems development; * Experience at least 3 year in development and implementation of health IT systems. * An experience in other area of working with additional proofing practice may be accepted in lieu of the health IT systems development experience. * At least one Laboratory information system implemented and successfully working in the Republic of Moldova; * Experience in configuring IT solutions in Cloud Platforms working in the Republic of Moldova; * Troubleshooting common IT problems; * Theoretical and practical expertise in all aspects related to data management, including database architecture; * Ability to design and implement effective IT solution, data architecture services and models to store and retrieve technical data; * Ability to examine and identify structural necessities by collaborating with technical programs; * Practical experience to develop, implement and assess database implementation procedures to ensure they comply with policies and regulations. * Proofing educational qualification of the staff involved to the electronic platforms development and implementation. * Working language for the assignment should be Romanian or Russian. |
| 1. **Supervision** |
| The experts  will work closely with the responsible technical officers:   * Dr. Stela Gheorghita, National professional officer, WHO CO; * Dr. Igor Pokanevych, WR, WHO CO Republic of Moldova |
| 1. **Location (including in-country missions, if any)** |
| Activities will be organized in Chisinau. |
| 1. **Remuneration and budget (travel costs excluded)** |
| Budget breakdown (see Annex 9. Financial proposal) |

1. Government Decision nr.951/2013 <https://www.legis.md/cautare/getResults?doc_id=103100&lang=ro> [↑](#footnote-ref-1)
2. The National COVID-19 Emergency Preparedness and Response plan, II-nd version, September 2020. <https://msmps.gov.md/wp-content/uploads/2020/09/Plan-r%C4%83spuns-COVID-19.pdf> [↑](#footnote-ref-2)