

## Volume 1 / Issue 1 Spring 2006 - Features

### Integrating LIS in Clinical Laboratories

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#### **The Urgency of the Problem of Automating Processes**

A Medical Diagnostic Laboratory (MDL) occupies a large part of the structure of diagnostic research, both in the quantity of research and the clinical importance of test results – which are important sources of diagnostic information for modern medical diagnostic processes. According to world statistics, in previous decades the quantity of performed clinical laboratory tests and their diagnostic importance exponentially increased – and continues to increase<sup>3</sup>. As the current business environment becomes more and more competitive, the need to emphasise the use of automation technologies to improve laboratory productivity, to accelerate research turnaround time and to maintain the quality of services is paramount.

Subsequently, the automation of MDL processes is an actual problem with significant practical value. The use of Laboratory Information Systems (LIS) has now become the standard of MDL activity, with MDLs using a variety of automated information systems. However, only a portion of these use an LIS, which unites all subdivisions of a laboratory as the common system. Nevertheless, a small proportion of hospitals have an LIS integrated with a clinical Healthcare Information System (HIS).

This article describes general issues related to the first steps of developing a unified basis for inputting, processing, storing, accumulating and analysing laboratory diagnostic data and improving the performance and quality of laboratory activity.

#### **Laboratory Workflow Peculiarities**

A macromodel of laboratory functioning follows a certain sequence of events. First, during input, research orders and biomaterial samples are registered and brought into correspondence with each other. Next, analyses (a set of laboratory tests) are carried out automatically or manually. The obtained results of these tests are then passed to a requester. The following peculiarities can be outlined at this stage:

- +test results (and their dynamics) are of great diagnostic importance;
- +there is significant document circulation between clinical departments and laboratories;
- +there are a great number of tests to perform;
- +there is an availability of efficient automatic analyzers (information which can be transferred);

- +there is a necessity to improve the reliability and quality of laboratory research;
- +there is a great deal of routine work completed by laboratory employees, and
- +the necessity of preparing laboratory operational statistics and the availability of scientific statistics.

All of these factors work together to propel the necessity of solving the problems of transferring and storing data, as well as the need to act responsibly to ensure the reliability and quality of publicly available laboratory research results. Therefore, the best solution to these problems is the use of modern IT technologies and facilities in laboratory activities.

#### **MDL Automation Goals and Tasks**

The automation of MDLs pursues the following goals and tasks: providing of Electronic Health Record (EHR) support; manipulating laboratory information in a digital data format for storing, accumulating, processing and transferring; finally, improving internal laboratory workflow processes by facilitating the routine work of laboratory employees. The subtasks of improving workflow processes include:

- +registration of research orders and order-sample authentication;
- +tracking and control of samples' traffic and status; departments and laboratories;
- +audit of samples' turnaround times and analyser's (laboratory equipment) use;
- +automatic import of data from analyzers;
- +automatic processing of tests results (norms conformity, calculating of indexes);
- +automatic generating of laboratory work books and operation plans;
- +tracking and planning of labour hours, and
- +generating operational reports and statistical data automatically.

In order to achieve these objectives, it is necessary to implement an information management system into an MDL. It is then possible to allocate two basic directions of laboratory activity automation<sup>6</sup> – the use of computers to automate information and workflow processes in laboratories, and the interaction of laboratories with clinical departments using a module-based HIS.

#### **Directions of Laboratory Activity Automation**

The first direction provides the use of computers for automating information and technical processes inside laboratories. Base functions of such systems include:

- + registration of samples and research orders, distribution of orders between laboratories, entry of tests results, and the operative and retrospective analysis of laboratory activity;
- + automation of research performing, including input and processing of data from laboratory analysers, and creating reports on equipment utilisation;
- + quality control of laboratory tests, the revelation and correction of mistakes, an estimation of the accuracy and correctness of analytical results and their statistical processing, and
- +registration of the reception and use of reagents & equipment.

The purpose of this direction is to increase laboratory productivity and research quality to take into account the use of reagents and materials, and to reduce the amount of routine tasks performed by laboratory personnel.

The second direction of laboratory activity automation deals with solving the problems of the interaction of laboratories with clinical departments on the basis of utilising a module-based common HIS<sup>1</sup>. Included amongst these problems are the automation of processes of laboratory research orders registration and the transferring of results to clinical departments, and the implementation of expert systems for attending physicians based on laboratory diagnostics<sup>2,5</sup>. Within the bounds of this direction the following functions are implemented:

- +the input of research orders from terminals in clinical departments and the delivery of research results to these terminals;
- +the creation of a database with the results of laboratory analyses and their accessibility to attending physicians for operative use, and
- +the automated support of medical decisions, including the granting of patient inspection programs, schemes of laboratory research orders, and methodical instructions on the interpretation of test results.

The main purposes of this direction aim to support attending physicians, reduce the delivery time of research orders to the laboratory, reduce the quantity of unreasonable analyses, and represent test results in a full and correct form.

## Requirements of a Laboratory Information System

Advanced Medical Diagnostic Laboratory Information Systems (MDLIS) should therefore support the functions of both directions of laboratory activity automation. The general requirements of an MDLIS as a subsystem of an HIS include:

- + conformity to domestic and international standards;
- + binding of EHR primary data and laboratory data;
- + support attending physicians with test results and their dynamics, and managers with statistic reports, and
- + access restriction control to laboratory data on ethic and functional rules.

General Requirements for an MDLIS Should Allow for:

- + the input of data manually and from analyzers;
- + a unified, scalable and customisable platform for any specialisation (biological, clinical, bacteriological, cytological, etc.); = research order creation from outside (physicians) as well as from inside (laboratory registrar);
- + data export in various data formats;
- + the ability to manage input data flows of research orders;
- + the ability to control the traffic of samples and the status of analyses;
- + registering checkpoint analysis times;
- + L/H visualisation and calculated index support, norms bounds checking in accordance with patient's age, gender and used reagents;
- + the generation of laboratory workbooks and operation plans on the basis of analysis data (order, results, executors);
- + to provide accounting of time expenses of test performing, and
- + preparation of operational and statistical reports in different slices.

Because an MDLIS is intended to be constructed on the basis of client-server technology with the use of RDBMS, allowing an MDLIS and HIS to share common information provides the optimal way to solve the problem of creating information analytical systems.

## The Solution

The first steps of any successful MDLIS development must include the investigation of a problem area and the formulation of the main objectives and requirements of MDL automation. In this case, the system was implemented within the bounds of research work conducted, the result of which was the creation of a scalable and flexible laboratory information system based on a unified data model. The resulting MDLIS was implemented both as stand-alone and integrated into an HIS in hospitals across Belarus and Russia, with the number of beds ranging from 200 to 1,500, as well as in a variety of different kinds of laboratories<sup>4</sup>.

The main goal for future work in this area is the realisation of information exchange between the diagnostic laboratories of multiple hospitals.



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