MLIMS for MRI

Implementation Medical Laboratory Information Management Software (MLIMS) for the Medical Research Institute

Version 1.7

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Project Proposal for Laboratory Information Management System (LIMS) for Medical Research Institute (MRI)

1 Introduction

A Laboratory Information Management System (LIMS) is a software system used in laboratories for the management of samples, laboratory users, instruments, standards, quality control and other laboratory functions such as invoicing, plate management, and workflow automation.

2 Deficiencies of the current manual workflow

- Data duplication
- Increased clerical work
- Transcription errors
- Unacceptable laboratory turnaround time (TAT)
- Misplacement of samples
- Difficulty in tracking a sample
- Difficulty in conducting research activities on available data
- Difficulty in generating statistical data

3 Objectives of the new system

- To eliminate data duplication by creating a single record at the specimen counter which will be accessed by the relevant department and sections
- To minimize transcription errors by limiting data entry to the specimen counter and the use of barcodes to track samples
- To reduce turn-around-time by streamlining the assigning of worksheets to lab technicians, minimizing data entry and rapid dissemination of results to requesting party through electronic media (email/fax/text message)
- To improve traceability by logging all actions performed at each location
- To securely store anonymous clinical data for future research, which includes the ability to view trends and to generate quality control charts
- To generate statistical reports for planning and monitoring purposes
- To comply with the international standards relevant to the system (SW, HL7 etc.)

4 Workflow

4.1 Specimen Counter

Specimens are received by MRI from all over Sri Lanka from government and private hospitals, MOH offices, and private individuals accompanied by a request from a general practitioner. It also receives samples from Judicial Medical Officers and animal heads for rabies diagnosis. Investigations are conducted free of charge for the government sector. A predetermined fee is charged from private samples. All samples are generally accompanied by a "Analysis Request" (AR).

- A single AR can only be from one patient, however one patient may have several ARs
- A single AR may accompany a single sample for the conduct of one test
- A single AR may accompany a single sample for the conduct of many tests in one department (eg: Serum Creatinine, Blood Urea, Serum Electrolytes in biochemistry department)
- A single AR may accompany a single sample for the conduct of many tests in more than one department (eg: TORCH screen is conducted by parasitology and virology departments: Then the sample is first sent to one department and once the test has been conducted it is passed on to the second department.)
- A single patient may have many ARs accompanying many samples for the conduct of many tests in the same or different departments.

Some samples may be rejected by the counter staff if they are found to be inadequate in quantity or quality. During the course of the day lab orderlies from relevant department visit the specimen counter to collect samples for testing.

Proposed Automated system

- The specimen counter shall be the entry point of a specimen and its AR in to the system
- The Medical Laboratory Technologist (MLT) on duty according to the roster under the supervision of the superintendent MLT shall be responsible for the data entry
- He shall log in to the system through an individual username and password only from the computer designated at the specimen counter and the logging information(person , time machine IP/MAC) will be available if necessary
- The system shall provide a user-friendly screen that will enable fast data entry through dropdown menus, search suggestions, and auto-generation of specimen IDs etc recognizing that usually specimens from one institution are entered as a batch. The

system shall prompt the staff member of any investigation that is not available at present or those that require an appointment.

- If the sample is from the private sector, an invoice will be printed and a charge will be applied. The system will provide a portal to the office, to accept payment from the patient
- The system will generate a unique specimen ID which will serve as the primary number for referencing and tracking a particular specimen. This number will renew each year.
- The specimen ID will be printed as a barcode which is pasted on the specimen and given to the requesting entity for tracing purposes (long-term goal)
- The system will generate a list of samples received for a particular department when the lab orderly comes to collect their samples
- At midnight the system will generate a list of all samples received during the day.
- The system shall present the MLT at the specimen counter an interface to search for a sample to respond to phone inquiries on its status.
- All samples will be barcoded at reception and this barcode shall be the primary identification method for a sample.
- The system will provide an online portal for an authorized person from a requesting institution to check on the status of a sample after logging in to the system through a username and password maintaining the privacy and confidentiality
- Once the result is verified by the consultant, the report will be automatically faxed to the requesting institution
- The system should comply with the currently governing health data and software standards (eg HL7& SW)

4.2 Department Reception/Chief MLT

The chief MLT or his designate shall receive the specimens brought by the orderly in to his department. Each department has several sections/benches where different investigations are performed. The system will automatically assign the designated MLT allocated to the relevant bench/section to conduct the test, with the option given to the Chief MLT to override.

4.3 Investigation

The system will display a list of investigations to be performed when the MLT logs in to the system. Some investigations will be performed by MLT immediately while others are processed as a batch when enough samples accumulate. Some investigations incorporate multiple in between steps that need to be traceable. For example, in histology samples may need to be cut, mounted, processed etc before the final reading is done. Most other investigations however are a simple one step process. The result of the investigation is usually a number with or without decimal values (eg: 10.14 mg/dl). In some instances the result is one of few possible values (eg: HbsAg - Poisitive/Negative/Equivocal, etc). Rarely the result may be a long description as in histology samples.

The MLT enters the result of the investigation in to the system. All numerical results may have a predefined "normal range" according to the sex and age of the patient. If the result of the investigation falls outside this range the system will generate an alert to the user.

4.4 Validation

The MLT will do the technical validation of the results, and they are forwarded to the consultant for final technical and clinical validation.

When the consultant logs in to the system he will be presented with a view of all completed investigations pending verification. The consultant will either verify or reject the result of an investigation. Direct editing of the result is not acceptable. He may add a comment or an observation to the report before verifying it. Only verified reports can be printed and issued. Rejected results will be added back to the MLTs queue for retesting. Once a report is verified altering it is not acceptable. If a mistake had occurred, a proper log entry should be made and a fresh record added to the system with the consent of the relevant consultant.

4.5 Test Reports

The final report will display primarily the patient's demographic details, details of the specimen and requesting institution and the test name with the result. Different departments may require some more additional details to be displayed on the report. Therefore the report format (template) may have to be investigation or department specific.

4.6 Other scenarios

When one specimen is received for a profile of investigations that involve two or more departments, the sample will first be sent to one (predetermined) department. The second department would know that such a sample is inbound but at the moment it is located in another department. Once the first department finishes their analysis, the sample is forwarded to the second department who receive it as per usual.

The system should follow the currently governing software standards e.g. ISO/IEC 90003:2004 and IEEE, as well as internal documentation standards, eGovernment policy of Sri Lanka, draft eHealth guidelines and standard of Sri Lanka.

All the available machines at the time of system implementation begins should be interfaced to the proposed system and should be included to the total system charges.

Once the proposed system is initially implemented in two to three units at MRI, it should be extended to whole MRI within three months to six month period depending on the status of the system mentioned below.

If the proposed system is not piloted anywhere before, the system should be undergone a minimum of 6ix months to one year pilot period. Then depending on the **user satisfaction &** after proper evaluation only the decision will be taken whether to continue or not. For a fresh system the **pilot period** should be not less than **six months** after implementing at all relevant units in MRI.

If the proposed system is well implemented/ piloted somewhere else before, the system should be implemented initially at whole MRI and after **three months** of successful running of the system along with the **user satisfaction** the decision will be taken whether to continue or not.

The selected system vender will be offered an initial payment of 16% of the total software charges and the rest of the amount will be paid only after the decision is taken whether to continue and the full payment will be paid in installments as stated below and the maintenance of the system and user training should be carry out free for minimum of one year **after completing the successful implementation at all units of the MRI**.

Payment plan for the proposed system,

Installment	Amount as a percentage of total	Description
1st	16%	With the purchase order
2nd	50%	After successful piloting if applicable and successful completion of all units at MRI with user satisfaction

3rd	22%	At six months of completion(excluding period of piloting if applicable)
4th	12%	At three years of successful completion (excluding period of piloting if applicable)

The maintenance of the system after the initial one year period should be not less than another four years and 10% of the total system fee can be paid as annual maintenance fee for each successive year after the first year of free maintenance.

12% of the total software cost will be kept as a hold and will be released after three years of complete system implementation or well before that, if the authority decided that no more annual maintenance is necessary by the software vender.

The source code if applicable should be handed over to MRI prior to initial payment exceeding 30% of the total cost and code verification and deployment verification will be carry out with expertise with the initial installation to minimize the issues of sustainability and will not be used for any other institutions without authorization by the software vender (proprietary rights will be safeguarded).

In case the proposed system which was selected is failed to complete during the stipulated period the initial payment of 16% of the total cost (1st installment- mentioned in the payment plan) should be returned to MRI within thirty days.

5 Requirements for Phase II

This phase of the process will be implemented close to the completion of one year piloting of a newly generated SW which is not tested before and by the end of piloting the phase II should also be completed.

The processes planned for phase II,

- For private/ government hospital samples, once the result is verified by the consultant, an SMS alert is sent to the patient that the report is ready for collection.
- The relevant reports will be available to download once the report is ready by the relevant person maintaining the privacy and confidentiality.