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LIS Integration and Implementation Process from Customer Perspective – Survey and Interview

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Abstract

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Laboratory information systems (LIS) are software solutions to record, manage and store patient research data in laboratories. This thesis studied the effects of LIS integration from the customer perspective and aimed to answer three research questions. The research looked for answers how LIS integration and implementation reduce manual labour in laboratories, what are the long/short term benefits of LIS and how LIS orientated field service specialist could improve LIS integration projects.

The research was conducted using qualitative research methods. The background of the study was composed through literature research. The practical methods used were systematic literature review, customer survey and interviewing. Selecting different methods allowed to study LIS from different perspectives and created a comprehensive idea of the systems. The data collected during the review, the survey and the interview were analysed to answer the research questions.

The results of the thesis show substantial benefits of LIS integration. Some results and beneficial features are subjective to specific type of laboratories. However many benefits were shared and common between different laboratories. These results can be used to improve planning of future LIS projects. Lists of recommendations for LIS projects were devised from the gathered data.

Keywords: LIS, LIMS, laboratory information system, laboratory information management system, laboratory workflow

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Contents

Abbreviations

AI: *Artificial intelligence.* Intelligence exhibited by computer systems.

CIS: *Clinical Information System.* Computer-based system to gather, storage and alter clinical patient data.

DBMS: *Database management system.* Software program that controls data creation, storing, managing and protection.

DNA: *Deoxyribonucleic acid.* The molecule that carries genetic information for the development and functioning of an organism.

dPCR: *Digital polymerase chain reaction.* Biotechnological refinement of conventional polymerase chain reaction methods that can be used to directly quantify and clonally amplify nucleic acids strands including DNA, cDNA, or RNA.

EDI: *Electronic data interchange.* System for businesses communicating information electronically.

ERP: *Enterprise resource planning*. Software for integrated management of main business processes of an organisation like accounting, project management, risk management and compliance.

GLP: *Good Laboratory Practice.* Established rules and criteria of a quality system to oversee processes and conditions of non-clinical laboratories.

GUI: *Graphical user interface.* Digital interface including graphical components like icons, buttons and menus.

HIS: *Hospital Information System.* Element of health informatics focused on administration of hospitals.

HL7: *Health Level 7.* Not-for-profit, accredited organisation providing framework and related standards for the exchange, integration, sharing and retrieval of electronic health information.

HW: *Hardware.* Physical parts of computer/device/instrument.

ICD-10: *International Classification of Disease-10.* Standardised system used to code diseases and medical conditions (morbidity) data.

ISO: *International Organization for Standardization.* Independent, non-governmental, international standard development organisation composed of national standard organisations of member countries.

IT: *Information technology.* Fields of technology encompassing computer systems, software, programming languages, data and information processing and storage.

IVDR: *In Vitro Diagnostic Regulation.* Regulatory basis for in vitro diagnostic medical devices on the European market.

LIMS: *Laboratory information management system*. A software-based solution with features that support a modern laboratory's operations.

LIS: *Laboratory information system*. A software-based solution with features that support a modern laboratory's operations.

LOINC: *Logical Observation Identifiers Names and Codes.* Terminology standard for health measurements, observations, and documents.

MS: *Microsoft.* Microsoft Corporation is an American multinational technology company.

PCR: *Polymerase chain reaction.* Method used to make millions to billions of copies of a specific DNA sample rapidly, allowing amplification of a very small sample of DNA.

QMS: *Quality management system.* Collection of business processes focused on meeting customer requirements and enhancing their satisfaction.

qPCR: *Real-time polymerase chain reaction.* Laboratory technique of molecular biology based on the polymerase chain reaction (PCR).

RDBMS: *Relational database management system.* Software program that controls data creation, storing, managing and protection.

RNA: *Ribonucleic acid.* A nucleic acid present in all living cells that has structural similarities to DNA.

SaaS: *Software-as-a-Service.* System that allows cloud-based apps over the internet.

SDMS: *Scientific Data Management System.* Electronic document management software to collect, organise, retrieve and storage digital files and data.

SNOMED: *Systemized Nomenclature of Medicine.* Systematically organised computer-processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting.

SQL: *Structured Query Language.* Domain-specific language used to manage data, especially in a relational database management system (RDBMS).

SW: *Software.* Programs used to operate computers and perform specific tasks.

TAT: *Turnaround Time.* Amount of time taken to complete process.

TB: *Tuberculosis.* A disease caused by a bacterium called Mycobacterium tuberculosis.

UPS: *Uninterruptable power supply.* Type of continual power system providing automated backup electric power when main power fail.

1

1 Introduction

This thesis was conducted over the course of 2023 and 2024 for the company the author works at. The company specialises in sample to insight technologies to better understand deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins. The product portfolio of the company includes sample and assay technologies, automation systems and bioinformatics. Some key product areas are digital polymerase chain reaction, tuberculosis testing, sample preparation and laboratory instrumentation.

The study subject of this thesis is to focus on the impact of the integration of laboratory information system (LIS) into the clients workflow. The study was conducted via literature research and review, surveys, interviews and analysis of the collected data. The study focus on the client perspective and compare LIS integration versus non-integration. As the company lacks data of the benefits of LIS integration and how a LIS focused field based employee would benefit customers this was an interesting opportunity to study these aspects. The customers are varying providers of laboratory services in Finland.

The research questions of this thesis are:

- How does diagnostic laboratory workflow improve by integrating laboratory information system by reducing manual labour of laboratory technicians?
- What are the short-term/long-term effects of LIS integration versus non-integration?
- What are the effects and benefits of a field based LIS integration specialist for the company?

The first research question intends to examine the improvements in manual labour reduction by implementing of LIS integration. Desirable benefits include but aren’t limited to saving labour resources for other tasks, faster diagnostic processes and cost-efficiency. The second research question focuses on

comparing in detail the effects of integration versus non-integration. This will create measurable data for the company and the customer to work on later on and could benefit both parties. The last research question aims at deepening the author's knowledge of LIS integration projects within the company's projects. This kind of specialist would understand the needs of the customer and could work as an on-site support for the customer and as an interpreter between the customer, LIS provider and the LIS support team at the company.

The core of the data collection for this thesis are customer surveys and an interview covering many aspects the customers experience during their LIS usage. The interviews are cross-cutting through the different layers of laboratory workflow, from the manual workers all the way to the decision makers. This way the benefits can be seen from all the different angles of the LIS usage throughout the whole process. The collected research data is subjected to the analysis methods for the final results.

This thesis focuses on LIS and systems, applications and instruments related to LIS integrations. The study introduces LIS technology in general, the main differences between LIS and laboratory information management system (LIMS), searches different integration deployments, creates integration solutions, processes results and finally summarises the totality of the thesis. The thesis also examines how these systems may be utilised further in the business model of the company. The solution created during this thesis won't be the final version ready to be published but rather an approximal solution for future versions. The thesis doesn't have to be optimised all the way nor does it have to fulfil all necessary cyber security related regulations. This thesis as well as the solution must answer the research questions. It is a necessity for the thesis to provide information how LIS integrations may be deployed by clients by utilising literature and information at hand of similar solutions.

2 Research Framework

2.1 Scope and Background

Originally this thesis was to be conducted alongside a customer LIS integration process which was cancelled thus the timetable of the research stretched from early 2023 to late 2024. The idea behind the thesis was born from the need of the company providing LIS integration for the laboratory instruments that the company manufacture. Lacking a field based employee specialised in the whole LIS integration process creates a professional vacuum within projects. The whole process is a somewhat group effort of many different operators. Whether it be the company's field based employees installing the instruments on site and making it possible for the remote company LIS specialised team helping in getting the instruments to be able to connect to LIS, the local hospital or laboratory IT team making the network connections work on site and the LIS provider creating the LIS interface in a manner that works for the needs of the client.

Despite the cancellation of the customer project the conclusions drawn from the surveys and interview can be of value to the company as it is still concrete data on LIS from the customers perspective. The thesis subject of LIS has fully supported professional growth in deepening knowledge of a field formerly having a lesser and more superficial role in the authors professional duties. Having more knowledge in LIS integrations as an employee was one of the main goals for the company over the process of this research. The company highly values professional growth, re-educating and training of its employees.

2.2 Research Problem

The company has a need for a field based LIS specialist that would understand the needs of the customer and could work as an on-site support for the customer and as an interpreter between the customer, the LIS provider and the LIS support team at the company.

The purpose of the research is to map out the possibilities how LIS integration process with a LIS orientated field service specialist would benefit the whole LIS integration process. Goal of the research is to have concrete data how LIS integration process benefits the customer workflow and how a field based LIS specialist would improve the company's processes.

The data is predicted to provide information regarding the benefits of LIS as a service and aids in enhancing the service provided by the company. Improvements based on the gathered data may help in advancing the company's digital LIS services and field based LIS services thus creating value for customers and the company alike.

2.3 Research Process

The overall research process started roughly around early 2023 by mapping out possibilities within the company to participate in customer LIS integration projects. In the beginning this would mean having a basic idea of LIS e.g. having coffee table conversations with colleagues and customers, researching websites of companies offering LIS solutions and furthermore having remote meetings with the company managers and LIS specialists. Idea was to get accustomed with the subject and process of LIS integration and then start working on customer projects. One suitable project was under works during the first half of 2023 but in the end this project was cancelled due to undisclosed reasons. At this point the thesis was to utilise research methods suitable for LIS integration processes such as time motion studies and cross benefit calculations. The methods are useful for situations where a business drives to reduce its costs to become a low-cost and high-volume producer. However the cancellation of the project deemed these methods unnecessary. Due to the nature of this early work most if not all of it is undocumented. [1]

2023 was used for the background research for the topic of LIS and figuring out new approaches for the thesis. The new idea for the research was to study the effects of a fully integrated LIS. This was done through literature research,

literature review and practical methods, in this case surveys and interviews, on existing laboratory instrumentation at customer sites. The process of literature research is to give background for the thesis by building the theoretical concepts of LIS and deepen the authors knowledge of the subject for the practical phase of the research. Without theoretical understanding of the subject the practical research would be harder to conduct and implement. Thus theoretical research creates a more comprehensive idea of the subject.

Practical phase continued from the theoretical phase by conducting customer survey regarding their LIS and their user experiences during the first half of 2024. These surveys were sent to differing laboratories throughout Finland from large municipal diagnostic laboratories to smaller private research laboratories. The survey got fairly good answer percentage but the material varied from rather superficial to more in depth answers. Thus the material gathered with the survey varied largely from customer to customer. Again, in addition to the survey, some coffee table conversations at customer sites and with colleagues at the company premises were had to gather some everyday knowledge of LIS.

Lastly more in depth interview was arranged with LIS orientated application specialist. This interview revealed information with much larger scope than the surveys were able to gather and the conversation dug deeper into the subject in more personal level. The interview was recorded and then transcribed for analysis.

These results could be used, for example, scenarios like how the situation compares between integration versus non-integration, what are the short-term and long-term effects of LIS integration at high input clinical laboratories and the effects of a field based LIS integration specialist working with the customer.

The research was concluded with analysis of the gathered results from which the conclusions were drawn. The conclusions gave space for some personal thoughts regarding the process and how to utilize the material gathered for future use.

2.4 Thesis Structure

This thesis is comprised of eight chapters starting with chapter one, introduction, which introduces the main idea and focus of the thesis. The second chapter explains the thesis process in a more detailed manner e.g. the background and the parties involved in the thesis.

The third chapter delves in to the topic of LIS through literature research explaining the concept of LIS thoroughly. As the theoretical frame of the thesis this chapter includes most information needed to understand laboratory information systems. The literature research material supports the material found in later chapters and gives framework for the practical part of the thesis. Pictures and lists help in visualising the different aspects of laboratory information systems without prior knowledge. The chapter is wrapped up with a literature review of selected background research material.

The fourth chapter presents LIS integration and implementation deployment process interpreting the different phases of such project. The phases detail different aspects that need to be taken into consideration during the deployment process with pictures to support the data on the actual physical act of implementing LIS integration. The implementation process includes different project task structures, activities, organizational structure and evolutionary stages of LIS systems with pictures helping visualising the concepts. Data presented in chapter four builds on the information presented in chapter three. The end of the chapter represents recommendations for a successful LIS integration and implementation project.

The fifth chapter focus on the methodology of this thesis showcasing the different practical methods used during this research. The sixth chapter analyses the data gathered during the practical methods introduced in chapter five and how this data could be put in further use. The analysis is used as a base for any improvement ideas that surfaced during analysing the data.

The seventh chapter concludes the thesis with discussion and conclusions. The chapter includes handling the results, discusses the learning process of thesis writing including personal thoughts throughout the process and what the future beholds.

2.5 Stakeholders

The stakeholders in this research were evident as the groups involved were the company (as the provider of LIS integration for diagnostic instruments and the instruments themselves) and the customers (LIS users) which could be divided to municipal diagnostic laboratories and private diagnostic and research laboratories. Having conversations with the groups and understanding the needs of all parties involved gave a profound idea of what LIS are, what is expected of them and what the systems could possibly be.

The customers involved in this research are users of the company's different services including but not limited to LIS integration and diagnostic instruments. The systems provided by the company are configured and adjusted keeping in mind the customer's needs and expectations. This could include adding or deducting different work phases, protocols and other additional services. Nevertheless the services provided should always have the customer's best interest in mind.

The company holds special interest in the research material as it might open ideas for improvements thus making the company the major stakeholder in this study. With customer network spanning around the globe the company is always open for refinement of its services. The company groups that can be seen benefitting from the study most are the LIS integration team and application specialists of the different national teams.

2.6 The Company and Laboratory Information Systems

At the moment the company provide LIS integration for several instruments that cover functions like nucleic acid extraction, real-time polymerase chain reaction

(qPCR) or a combination of these two, instrument for rapid qPCR and customised service for pipetting robot used for automated polymerase chain reaction (PCR) setup.

Features provided by the company's LIS integration bring benefits to laboratories like:

- Improvements in workflow quality
- Elimination of errors from manual entry of data
- LIS with bi-directional communication
- Interaction modes for LIS
- Accurate and fast results

The company also provide LIS integration for instruments from third party manufacturers. The company can design custom pieces of software (SW) which communicate with the company's instrument and other manufacturers instrument and result back to LIS.

Main challenges that the company face when implementing LIS integration for customers is getting everything aligned. It's challenging as there are several stakeholders involved in the discussion like the customer, a LIS provider, the IT department(s) and the company as the implementor. You could say that the company is the conductor of an orchestra that coordinates several people from different departments and makes sure what's who's responsibility. For the customer it would be essential that they experience as few interruptions as possible while the company work in the background. Sometimes the customer may need to help the company to provide their needs for the LIS to fulfil their expectations. However the main focus is that the customer expects the instrument to report through LIS without interruptions.

One of the main problems the company have at the moment is that the company doesn't have a field based employee specialised in LIS integrations so that the company could improve LIS integrations on site. The company do have LIS integration service team that work with the LIS integration remotely and create solutions for the customers' needs. The company also lack test protocols

for the LIS integration service team however these tests can usually be conducted by the LIS provider.

By having a field based LIS specialist the company would fill the gap in knowledge in the author’s team to help the customers with their issues onsite. This would reduce workload so the company could see that there is a need for this kind of employee. By implementing field based work from the start of the LIS integration it could be measured whether it makes any difference to the process. Also the benefits for everyone involved in the project could be revealed. Obviously this would require the need to deepen the knowledge of LIS for field based employees and the whole process involved in LIS integration. Covid made the company step back from focusing on this kind of improvement but the future holds possibilities to refine the current situation.

3 Literature Background

This chapter describes LIS and LIMS in extensive manner. These two terms will be utilised almost interchangeably during the chapter but in order to simplify things LIS is the preferred term throughout this thesis. The chapter reviews the benefits of LIS and LIMS and relevant applications for the system. This chapter also gives answer to the first research question. The thesis focus around LIS and how the integration process of implementing LIS to an existing laboratory workflow will benefit the laboratory and its workers. The customer perspective is the key point of view in the thesis. In order to prepare for the survey, the interview and the overall practical process of the thesis thorough literature research was conducted. The theoretical background research helps to understand the basic principles of LIS and sheds light on the topic for the unacquainted.

3.1 Laboratory Information and Management Systems

The need for a system like LIS rose from being able to manage analytical information like testing data as a whole. The first LIS were developed in the late 1960's by individual organisations which then were later commercialised early in the 1980's. Before the introduction of LIS laboratory results were mostly recorded on notebooks. Table 1 represents the LIS evolution from 1970's to present. Clinical laboratories in hospitals were the first laboratories to utilise LIS. Later on the systems became common also, for example, in pharmaceutical companies. In the 1980's there were eight commercial LIS available which then grew to over 50 companies offering LIS products in the 1990's. The 2000's saw development of broader, more flexible and more advanced LIS requiring less customisation than earlier versions. It was estimated that in 1991 the worldwide market for LIS was at 130 million US dollars including aftermarket support and services. In 2022 the global LIS market was analysed to be at 2.01 billion US dollars according to Data Bridge Market Research. [3] The market is expected to grow further and reach 3.86 billion US dollars by the year 2030. [2, p.1-4] [4, p.2] [5, p.12]

Table 1. History of LIS. [5, p.12]

	1970-1980	1980-1990	1990-2000	2000-
Data Recording	Pen and paper	Pen and paper	PC	Bar coding
Data Analysis	Slide rule and calculator	Calculator and first LIS software	LI(M)S software	LI(M)S software (PC or web based)
Data Storage	Paper-based logs	Books	Electronic database	Electronic database
Report Generation	Typewriter	Typewriter and word processor	Standalone computers	Electronic
Report Sharing	Postal mail	Postal mail	Fax and email	Electronic

According to Nakagawa it is highly subjective what the exact definition of a LIS is. [2, p.9] The definition is dependent on the group of people defining what LIS consists of thus leading to different definitions that may be diverse and conflict with each other. Different organisations, different laboratories within these organisations and even individual laboratory personnel within the laboratory group may disagree on the exact definition. This lack of standardised definition may determine LIS implementation a cumbersome process. LIS has to deliver and meet with the initial expectations given by the users and funding otherwise the system will fail. The more people and groups are involved the more the expectations differ within the community. [2, p.9]

Nakagawa says that implementing LIS successfully depends on the organisation consolidating their expectations of the system despite any current standards or definitions. [2, p.11] According to Skobelev et al. LIS is defined as a SW application dedicated for storage and managing of data and information acquired from laboratory work. [6] LIS controls and manages samples, test results and reports, laboratory staff and instruments as well as automation of workflow. LIS enables sharing of data for applicable personnel with ease which aims to help in finding the correct information in a flexible manner, definite saving of results and forwarding the information to whoever it may concern.

There are certain minimum requirements for LIS that are expected. These high level requirements shown on the diagram on Figure 1 are referred to when acquiring a potential system. [2, p.11] [4, p.3] [5, p.66]

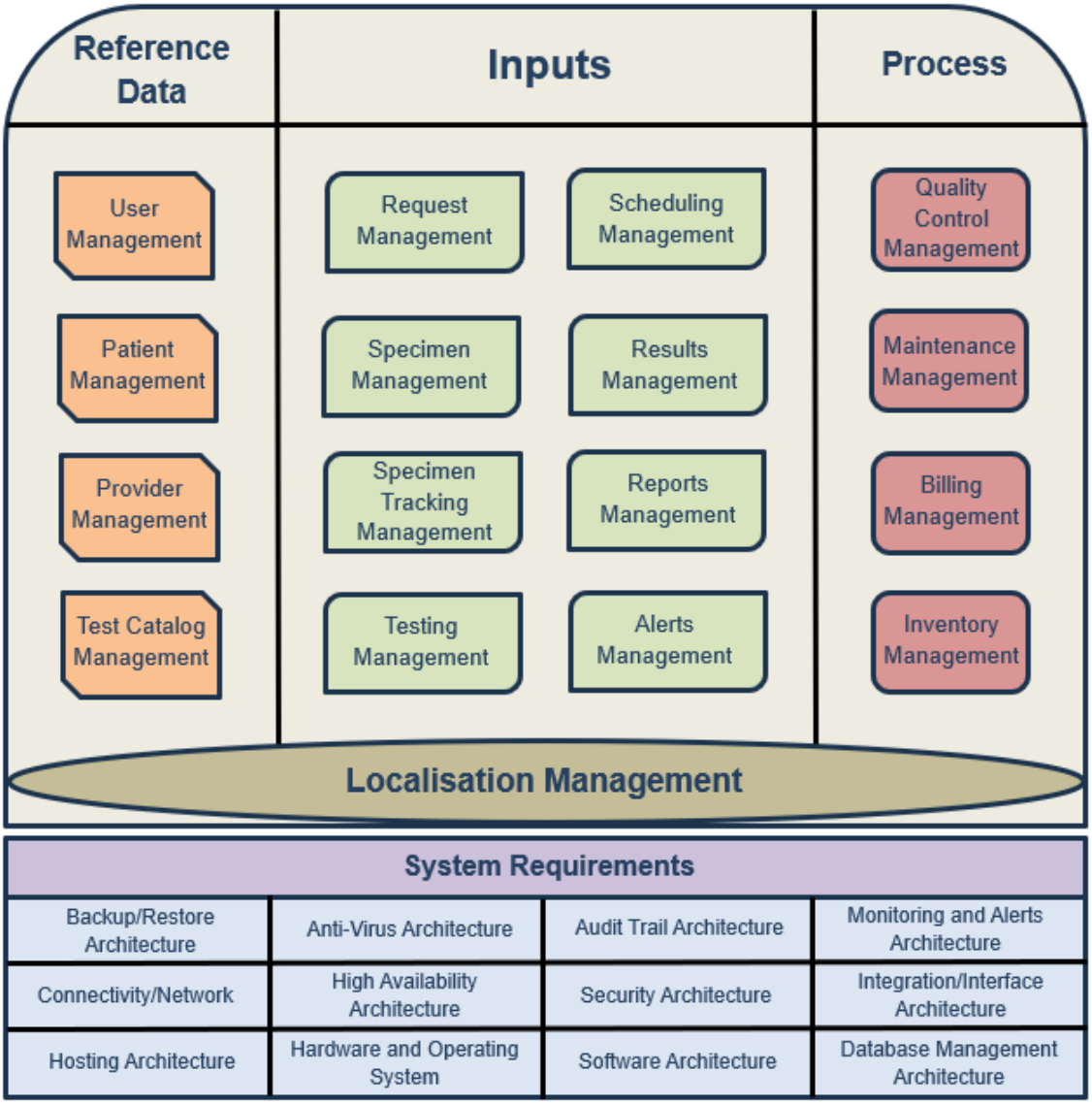

Figure 1. High level requirements for LIS. [5, p.66]

LIS consists of group of components that are related and interacting by function to support a common set of objectives. LIS is built of manual and automated components from which the automated features include delicate computerised hardware (HW) as well as SW technologies. The manual components of LIS vary from system aspects related to organisation, procedures, personnel and management. Systems may be closed or open main difference being who may

or may not access the system. In closed systems those who manage the data are able to restrict access to the system and in open systems data and system access are management by separate entities. Generally speaking all LIS are closed systems. Many of the modern LIS are browser based and can be accessed from the users own workstation and even outside the laboratory. The different components building the basic workflow of LIS is depicted on Figure 2. [2, p.11] [4, p.2-3]

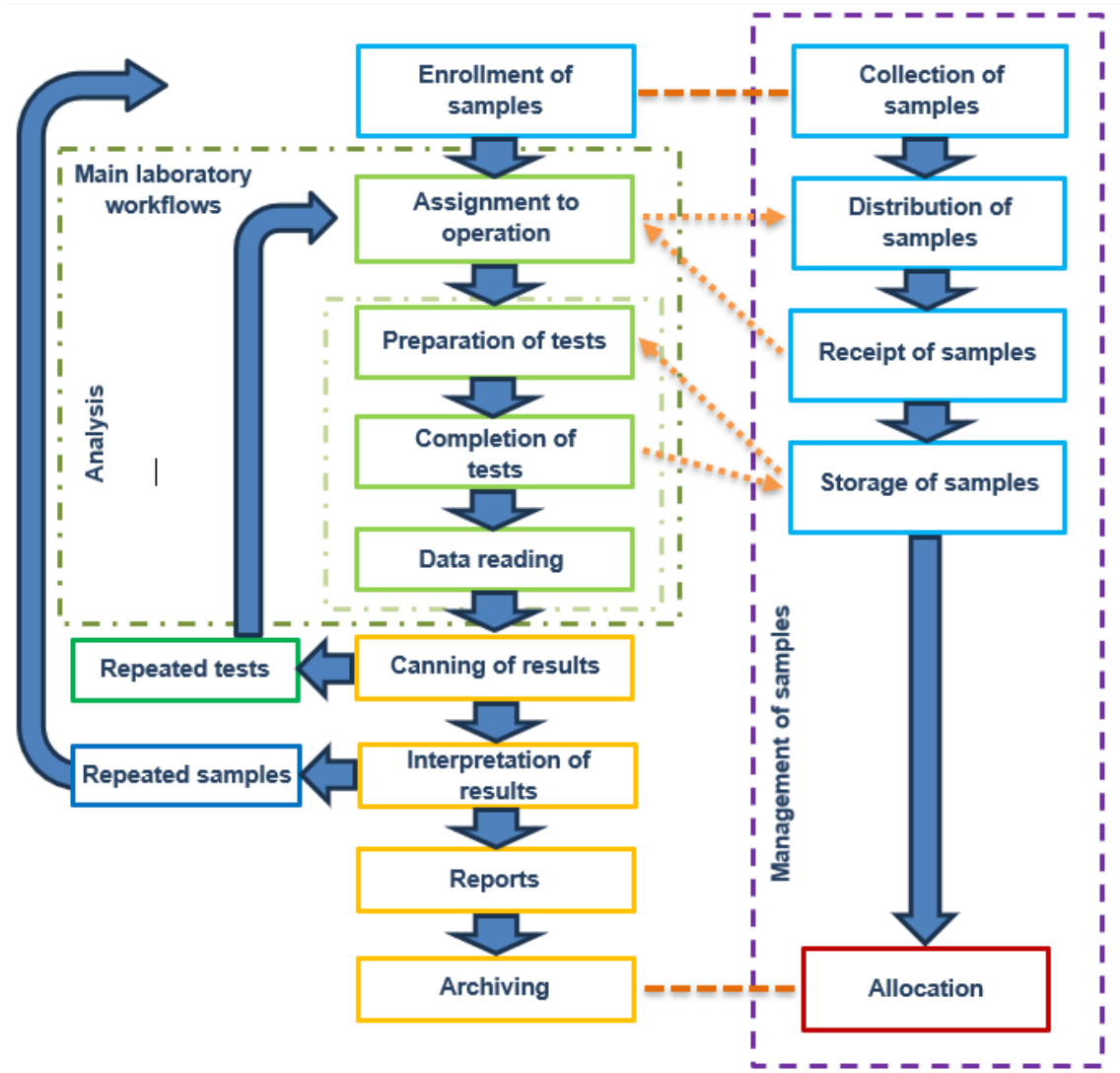

Figure 2. Basic LIS workflow. [6]

Modern laboratories require automation in order to perform analytical studies efficiently which in turn requires successful implementation of information management system. However modern LIS do not pursue full automation of laboratories, as some test processes need to be performed manually, rather the systems are used for parsing and handling of information. LIS to instrument interfaces are available in uni-directional (one way) or bi-directional (two-way). Uni-directional systems are limited for automated or manual transfer of data from instruments to LIS. Some instruments only support uni-directional interfaces. Instruments supported with bi-directional interface are able to receive information from the LIS and then transfer the results back to LIS. [4, p.2 & 15] [7] [8]

LIS can be divided into five basic stages:

First stage, sample enrolment received by the laboratory which may be manual or automatic. This includes unique identifier like line code or enrolment number, adding specific information to LIS like customer data, sample description, security information, sample storage conditions, tests to be performed, costs etc. [6]

Second stage, samples are assigned to analysis meaning distribution of analytic work in the laboratory. The tests to be performed are listed on the system including information regarding requirements like material quantity for each test and where the samples will be sent for analysis. In this stage a graph may describe functions like monitoring assigned analysis execution, time tracking for sample analysis and reminders for personnel to run certain analysis. Sample distribution determines also when samples may be analysed at different laboratory sites and helps management to determine capacity, status and delays for certain analysis. [6]

Third stage, processing analysis proper which includes preparation of sample, measures to be carried out like quality control, generation and collecting of information and repeating tests if necessary. After sample preparation the input of samples to the LIS occur in measurement order. Completion of samples is

followed by various data like instrument adjustment parameters, additional sample information, defects observed and any other difficulty or unusual behaviour of the instrument are then input into the LIS. This stage helps in tracking usage of reagents, equipment, personnel and the need for calibration or repair activities. [6]

Fourth stage, LIS obtains the input of results which may be input manually or automatically into the system. Automatic input of results requires LIS to be integrated to the laboratory instrument. Record to certify analysis of results is created which can be checked to ascertain that results are within acceptable range. Unusual and results falling outside the acceptable range can be marked for further study. [6]

Fifth stage, this stage consists of test result inspections and compilation of different reports and the function to scan, indicate quality of samples and approve or reject test results that need to be incorporated in the LIS. LIS creates audit trails which could include data like invalid sample results due to repeated but failed test run. LIS may generate the end results in electronic or in paper form. [6]

Main difference between LIS and LIMS is that LIS is developed for individual patient records compared to LIMS which is used for batch testing. Sometimes the terms are used interchangeably and even the two do overlap in functions. They were meant for different laboratory types as mentioned before however the scope of LIS is narrower. LIS is best suited for clinical laboratories and diagnostic laboratories to manage patient information, specimen tracking and test results related to healthcare diagnostics. Key focus areas are patient management, test orders, healthcare diagnostics and integrable to hospital information system (HIS) for smooth data exchange between laboratory and healthcare personnel. Figure 3 presents LIS' relation to HIS. [9] [10]

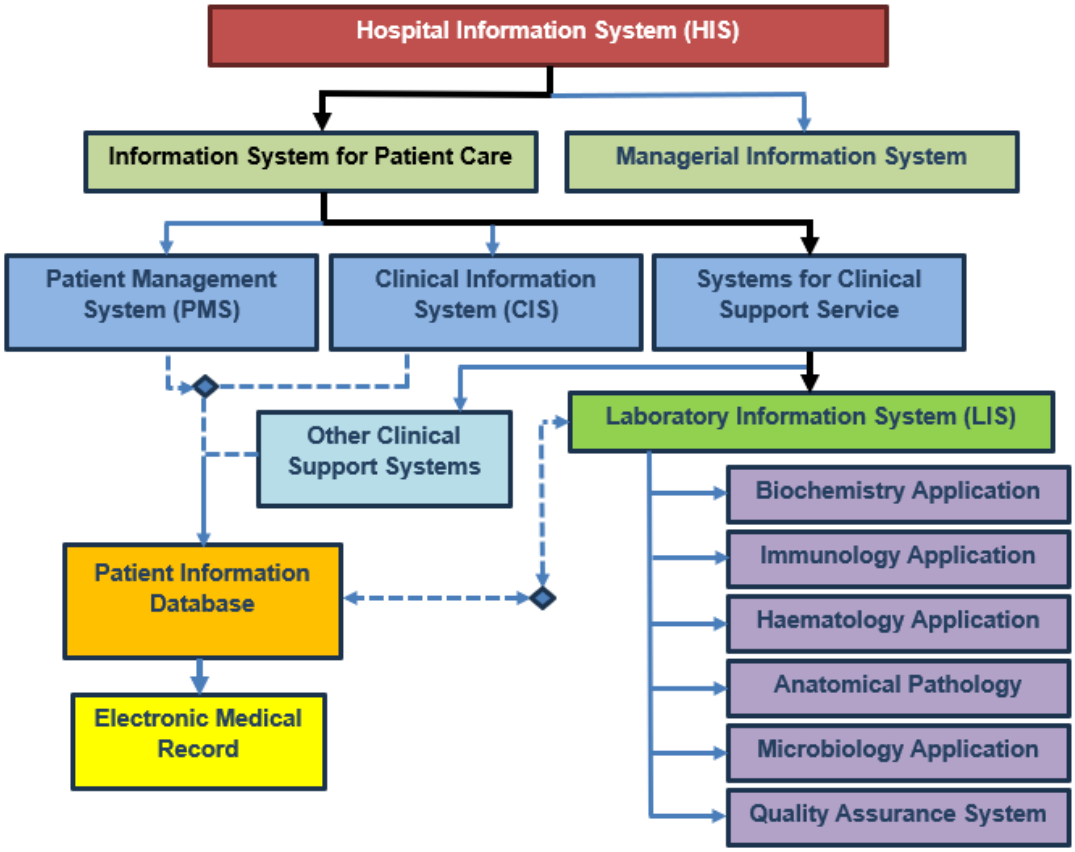

Figure 3. LIS' relation to HIS. [8]

LIMS is more suitable for clinical research or nonclinical laboratories specialising in laboratory operations focusing on sample tracking, protocol execution and data management of specified scientific research and testing. The high customisability of LIMS makes it adaptable to many different scientific laboratory workflows whereas the needs of clinical and diagnostic laboratories guides how LIS functions. Both systems are integrable to other systems used in laboratories and healthcare. [9] [10]

3.2 Benefits of Laboratory Information Systems

The benefits of LIS regard on the definition of the system. This definition differ from people to people and excess emphasis on certain aspects of the system can constrain possible advantages deliverable by the system to the organisation. The sophisticated technology of LIS has to work in line with the manual business processes of the organisation in order to provide solutions. [2, p.11]

LIS may improve performance, efficiency and capabilities of the laboratory as the system changes notably the information handled in the laboratory. Organisational performance may also have negative effects if unanticipated effects occur and are not dealt with diligence. The range of the LIS implementation determines also the vastness of the impact these effects have. The variabilities effecting the LIS affect the workflow after the implementation. Such are the number of automated functions applied, the volume of samples processed and the amount of people using the system. It could be said that the more complicated the system is the more variability there is for positive and negative impact and vice versa. [2, p.11 & 75]

Regular laboratory labour procedures are altered by automation resulting in improvements in working ergonomics and differences in procedures like reduced manual information management. LIS also standardises processes for selected laboratory procedures through routine and consistent execution of tasks. These processes may have been previously undefined or inconsistent. Many tasks in the laboratory will have decreased work around time due to the integration like acquiring the status of a sample, testing etc. In one case a hospital laboratory used equal time for manual reporting and analysis of samples and by implementing LIS reduced the time to a fracture of what it was. In other words LIS reduces turnaround time (TAT) by increasing efficiency and productivity. [2, p.75] [4, p.5] [11]

Since LIS provides easy access to available information through database, work between different laboratory groups is more easily monitored. Formerly this information was generated manually. This eases the management of the different groups by allowing supervisors to concentrate on exceptions and conditions affecting the quality of service in the laboratory. Eliminating errors caused by manual generation of information is often said to be one of the most important benefits of LIS. By having electric referrals, sample recognition via barcodes and reducing mistakes of manual copying the risk of errors are minimised if not nulled. LIS enables integration to enterprise resource planning (ERP) and quality management system (QMS). These systems support everyday business activities and quality standards and regulatory requirements. For predictive analysis LIS is integrable to risk analysis and statistical tools. This is useful for the laboratory staff in eliminating issues in advance. Cloud-based LIS offer an easy access to data regarding of time or place, assures data integrity and confidentiality via secure authentication mechanisms. [2, p.75] [4, p.5] [11]

Important LIS functions include generation of all types of reports like quality certificates, test protocols, analysis certificates and adapting those reports to certain users. In order to generate reports, construct graphs and standardise report forms the LIS system should support standard SW products. This means also implementing electric signatures to the LIS. The user may also print reports or send them via email. If the system has implemented quality control component even the approval of results may be automated. This requires that certain thresholds have been defined for the system. In case the system recognises anomalies the system may alarm the user. Implementing LIS helps in standardising the operation which means following industry standards. These are the likes of International Organization for Standardization (ISO), the Principles of Good Laboratory Practice (GLP) and In Vitro Diagnostic Regulation (IVDR). This may help the laboratory to pass accreditations. Following standards also benefit the laboratory, for example, by allowing rapid response, improving patient management and case reporting and streamlining

workflow. The next section lists several benefits provided by LIS in a more detailed matter. [4, p.6] [5, p.68] [6]

Table 2. List of beneficial features of laboratory information systems. [2, p.14-20]

Sample Identification
Labelling: Labelling samples with unique barcodes will help identify the work by LIS.
Registration: Recorded description of sample type, source, date, submitter, priority, material type etc.
Log In: Records the date and time once the laboratory receives a sample.
Progress Tracking
Work Progress: Progress tracking of analytical work status states such as logged in, complete, cancelled and approved work.
Sample Location: Tracks the physical movement of the samples e.g. from a laboratory to another. Important in situations where chain of custody for samples has to be recorded.
Results creation
Test Data Entry: The database accepts and records the data and results of the samples being analysed.
Test Calculations: The LIS database records the data calculations performed by the method or protocol used.
Results Verification
Analysis Review: Provides review of completed test results, supporting data and could include other functions like correction of erroneous values and rerun of samples.
Analysis Approval: Sample results are released by authorised personnel.
Specification Checking: Checks that the result values are within acceptable range.
Analysis Modification: Modification of current tests like assigning more tests, test cancellation, repeating and resampling of tests.
Results Modification: Authorised laboratory personnel may correct result values that are entered incorrectly. Internal audits may require laboratories to record the time, the employee and reason for modifications.
Reporting
Results Reporting: The sample results are obtained, collected and formatted from the LIS database.
Results Distribution: Approved test results are distributed to applicable parties and/or transferred to other databases for record keeping, further processing etc.
Report Definition: Establishes and defines the information content and format of reports which may be created on demand by authorised personnel or at recurring schedule.
Ad Hoc Enquiries
Ad Hoc Query: Free form query displaying selected information either on screen, printed report or on a file.

Table 2 (continues)

Instrument Integration
Interfacing: Establishing a capable data transfer between the instrument and the LIS. Instrument interfacing means only the compatibility of the physical connections and data transfer protocols between the LIS and the instrument. Instrument interfacing doesn't ensure integration with the system but other functions are needed for the data transferring and processing. However without the interface the integration isn't functional.
Data Acquisition: Devices that converse instrument data into a computer recognisable and storable format.
Instrument Control: Instruments are mostly controlled via computers that are integrated to the instruments data system which include control of the instrument settings and operations.
Run Lists: The routinely run sample preparations, standards and blanks are presented on the run list but the actual sequence is ruled by the user or instrument programs.
Data Transfer: Movement of instrument data or data system to the LIS. This transferred data can be left outside of the database for data reduction and processing before transferred to the LIS database.
Data Reduction: Before the data is stored in the LIS database it is calculated, reviewed and processed further which may involve data from other instruments, sources and manually entered sample results.
Laboratory Management
Work Scheduling: Used for work assignment and distribution in the laboratory including work lists and worksheets.
Completed Analysis: Lists the completed tests of the laboratory/laboratory group including tests within a certain time period and also the service cycle of the laboratory. Creates insight for which activities are falling behind and need further investigation and also highlights the areas of improvements.
Incomplete Work: Backlog of total work of a laboratory/laboratory group. Helps in reallocating work or personnel and assists in foreseeing where improvements are needed or if the turnaround time of sampling is slipping from schedule.
Workload Demands: Lists all new work input during a defined time period. Helps in creating trend patterns of testing which helps to plan personnel and equipment needs.
Protocol Maintenance: Maintaining test methods, specifications, projects, studies and other laboratory specific protocols in the provided repository ensures consistent execution of protocols in the laboratory work flow.
Pricing and Invoicing: Maintains the basis of customer charges and cost allocations which may be test, sample or project based. For invoicing and cost allocations the system maintains uniform pricing policies. The services provided, their associated costs and terms of payment are itemised and overdue invoices and customer payment histories can be tracked by linking invoicing functions.
Cost Allocation: Distribution of costs of analytical services over a certain time period among laboratory clients including externally billed services and services provided within groups of the organisation.
Systems Management
Security: Functions to maximise system reliability and protection of data integrity e.g. SW and data backups, restricting access to data and programs and recovery during utility and other failures.
Data Archive: The optimisation of the system storage resources and improving the systems overall response time works through archiving less frequently needed data and removing it from the active system.
Data Retrieval: Archived data can be retrieved to the active system for auditory or investigative needs. To ensure successful data retrieval the data archives need to have appropriate data organising and indexing.

Tangible benefits provided by LIS can be identified as cost reduction, cost avoidance and revenue enhancement. LIS provides cost reductions by decreasing or eliminating operating expenses such as labour, materials, services and facilities. Examples are decrease of dead time and increase of equipment and personnel utilisation. Cost avoidance postpones, eliminates or reduces expenses by predicting future increase or changes in expenses such as growth in handling volumes. Enhancements in revenue focus on improving internal and external services and applications like data quality, report formats and customer service. Benefits are achieved through increasing the demand for the services and products of the laboratory by making them superior to that of others. [2, p.143]

Benefits provided by LIS implementation that could be considered as intangible are such as better sample tracking and quality of results, improvements in organising data, quality of operations and laboratory management. These are considered intangible as it is difficult to calculate monetary value for features that are tangible to some laboratories but intangible for another organisation. However inability to assign value to a benefit doesn’t make it any less important for the organisation. [2, p.143-144] [4, p.6]

To sum it up efficient LIS brings benefits to the laboratory and the company by increasing laboratory throughput, reducing test turnaround time, savings in labour and client time by optimising workload and improvements in data and laboratory management, reporting, data accuracy and consistency of quality results. The best results from LIS integration can be achieved when the company’s other parts may improve their actions based on information gathered through LIS. [2, p.89] [4, p.5-6]

3.3 Downsides of Laboratory Information Systems

Automation may produce feelings of separation from the physical efforts of the laboratory workers individual work thus altering the workers sense of accomplishment within their line of duty. LIS also causes the physical separation of information which for the user means that the information resides in a database instead of on a piece of paper. This lack of visual work load means that the information for work been done has to be obtained from the LIS database which might not be accessible for all the laboratory workers. Some studies dictate that only around 50% of work force has been satisfied with their LIS. According to another study there were no considerable difference in errors between manually entered and automatically entered patient data. [2, p.75] [4, p.11-12]

Inter personal interaction between laboratory personnel may reduce due to centralised information database which eliminates the movement of paper and other forms of direct information from person to person. This may alter working relationships and may even produce feelings of isolation from the working community thus lowering working morale and creating non-productivity. Early involvement of all the applicable users is crucial for them to acknowledge the new system and accept the change. Otherwise the result could be as proposed by Avery et al. below. [2, p.76] [13]

> “Resistance to change may be the biggest cause of failure in implementing a new system.” [12]

Introduction of automation via LIS renders some procedures inside the laboratory obsolete and possibly requires the laboratory personnel to acquire new skills to operate the new system to its fullest capabilities. However some skills may deteriorate due to automation as processes formerly performed by personnel are now automated. Over time some skills may be totally forgotten. Improvement in testing timelines creates an increased demand in workload thus increasing the intensity and pace of the work in the laboratory. [2, p.77-78]

LIS integration will add costs as the system needs to be maintained and supported by trained personnel. These costs will also include possible expendable supplies and service agreements. Also any change to the system needs to be performed by aforementioned trained personnel and needs to be agreed and evaluated individually. All this takes extra effort in planning how to run the system and may have economic impact. The HW side of LIS such as hard drives and network components are also subject to failure and will cause problems in the workflow unless the necessary resources are implemented to negate these issues. [2, p.79]

Some might see LIS as a solution for all data management issues in laboratories but automation doesn't automatically mean solving all errors and problems. Implementation gone wrong could actually increase issues within the laboratory workflow. On that note the system itself needs to be well designed as well. The system is capable of operating reliably only how well it was designed for its designated purpose. Errors in the system could lead to wrong diagnoses jeopardising the credibility of the laboratory's services. Following industry standards brings its own challenges when the laboratory needs to follow many standards and jurisdictions. This can be costly for the infrastructure to be put in place which needs to follow electric reporting and there's a shared effort between the laboratory and the LIS vendor. Also guidance and regulations need to be agreed on to support standard usage. [2, p.80] [5, p.68]

In order for LIS implementation to achieve increase in productivity the system needs to meet the needs of the laboratory, the system needs to be rapidly implemented and the personnel need to be well trained in the new system. Without these aspects there might even be a decrease in the productivity. Common mistake in LIS implementations is to underestimate the work needed to successfully complete such project. Configuring LIS takes a great deal of resources in order to get familiar with the product and defining laboratory operations. However configuring the actual details into the LIS is fairly swift. Implementation may fail due to rigidness of the system in case the system is

unable to improve with the internal processes of the laboratory and if the benefits of the system are hard to measure or unmeasurable. [2, p.80] [4, p.11]

3.4 Applicable Uses for Laboratory Information Systems

Different organisations provide different products and services and have their own market and regulatory statuses. These are the contributing factors for the services provided or their lack of. The analysis which the laboratory performs, types of samples analysed and the test results and their end purpose differ noticeably from laboratory to laboratory. Typically there are different sort of laboratories even inside individual organisations. These laboratories utilise and have their own equipment and technology, personnel and procedures depending on their unique needs. As LIS alters the workflow of the individuals and the laboratory there will be shift to previously recognised workflow patterns with the new system. Figure 4 showcases two different approaches that Companies A and B have took for their respective LIS to emphasize their needs. [2, p.11 & 75]

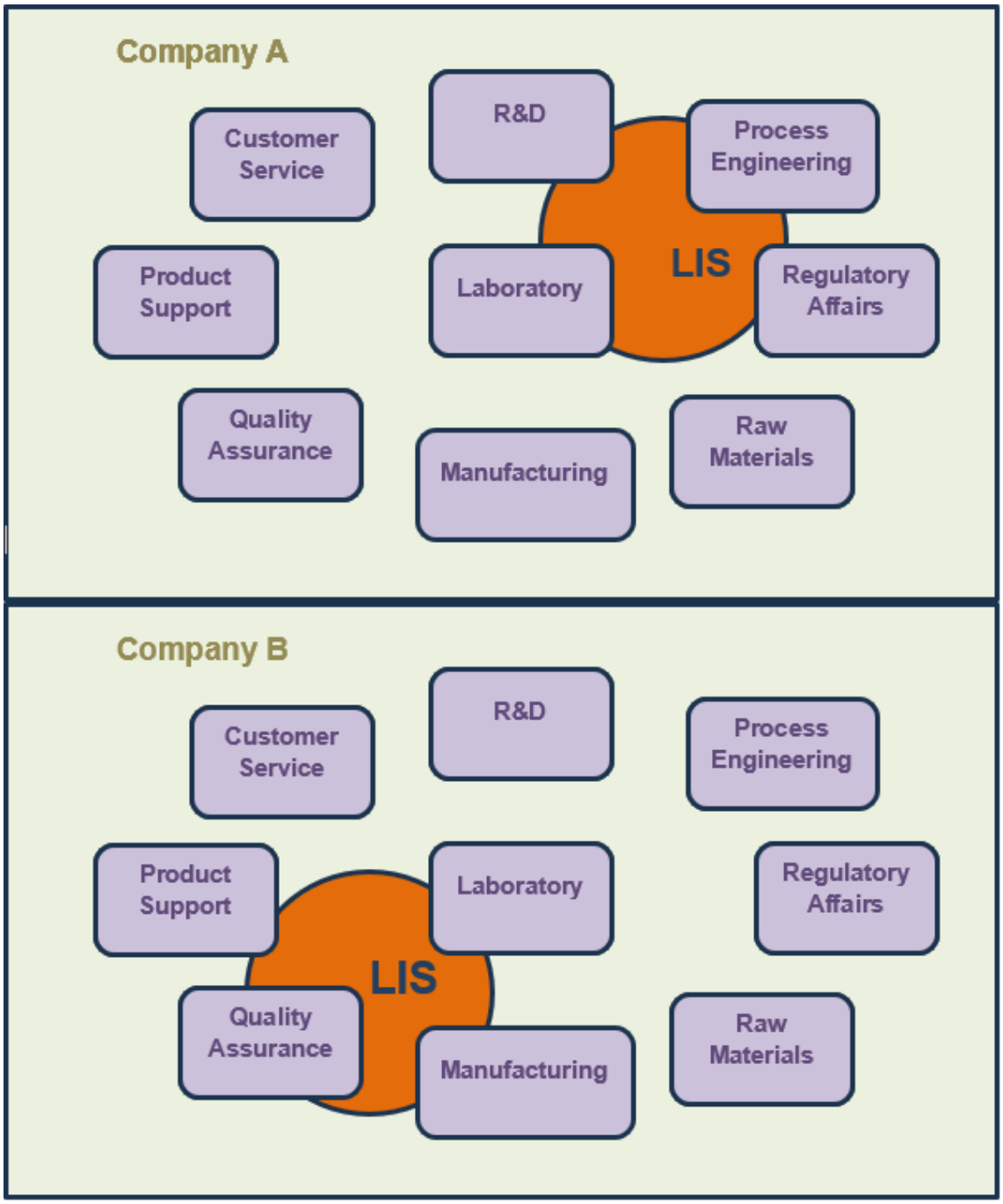

Figure 4. Two different approaches for LIS. [2, p.10]

The needs of the client and the results generated by the laboratory dictates the information handled by the LIS. Also the scientific discipline or disciplines of the laboratory has a big impact on the information the LIS handles. The data between, for example, microscopic analysis and chromatography differ greatly. The former includes specimen information, specimen image and examination conclusions and the latter includes recordings of detector response versus time

which are used to identify sample components and their concentration values. Figure 5 gives an example of possible functions connected to LIS. The importance of the different functions are relative to the laboratory personnels position and work tasks. [2, p.11]

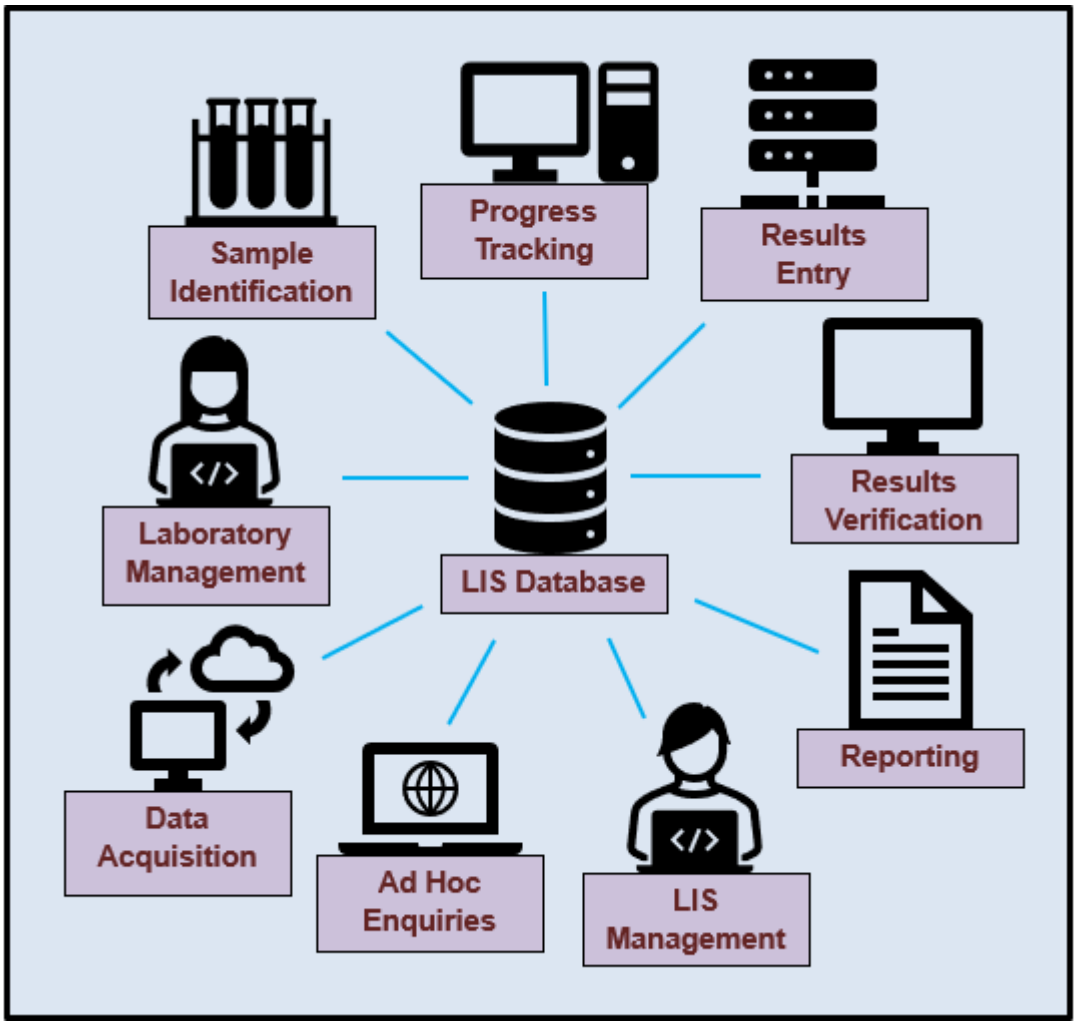

Figure 5. Functional model of a LIS. [2, p.14]

Generally there are two reasons to implement LIS. One is to fix issues or limitations caused by obsolete or ineffective manual or automated system that are not on level with current quality standards. Another is simply to improve the organisations automation and management capabilities in laboratory operations and data management. [2, p.90]

According to a survey by Strategic Directions International the most important characteristics of LIS are:

- Data and result input
- Sample enrolment
- Sample tracking
- Generation of reports
- Ease of use and training
- Application security
- Review and validation of results
- Report customisation
- Flexible and adaptable
- Compliance to standards [13]

The use of LIS varies between the different user perspectives. Here are different perspectives and further information regarding the perspective.

Business Executive Perspective: LIS enables improved handling of laboratory results for the organisation's business units thus improving aspects like customer service, product quality and development and the efficiency of operations.

Information Systems Perspective: Whoever is responsible for the information systems of the laboratory sees LIS as one of the organisation's database applications and how the LIS works together with the laboratory's other sophisticated HW and SW solutions.

Laboratory Perspective: For laboratory managers LIS helps to monitor the workload of a laboratory e.g. moving laboratory personnel to projects or groups where they are most needed and monitoring analytical turnaround as well as the service provided to their clients. Laboratory supervisors use LIS for tracking sample statuses and testing and the system assists the laboratory supervisor to keep track of completed and outstanding work orders as well as responding to client enquiries. For laboratory analysts LIS eliminates the burden of handling

paperwork, repetitive manual calculations, processing and transcriptions as well as help plan their work days more effectively and efficiently. [2, p.12]

3.5 Findings Based on Literature Background Research

The material which this literature review is based on are the books, the articles and the theses used for the literature background research of this thesis. The material was searched through Metropolia UAS' e-library service MetCat Finna and Google search. The different keywords ranged from "laboratory information system" to "laboratory information management system" and to their abbreviations "LIS" and "LIMS". Together with the aforementioned keywords other applicable words like "implementation" and "integration" were used. When searching with just the abbreviations the search results were less adequate than with the abbreviations or full words accompanying with other words.

MetCat Finna e-library found 398 search results with using just the abbreviation "LIMS". After reviewing these results two studies were selected for their relevance for this thesis. Searching MetCat Finna with just the word "LIS" produced 3710 search results. Surprisingly the search results were not of relevance probably due to the very general mix of letters without any context. Using the e-library for the words "laboratory information system" and "laboratory information management system" produced 393 and 99 search results with overlap in the top results produced. No studies were selected from these searches. With the word "implementation" added the search results were narrowed down to 59 and one promising study was found but not selected in the end. Replacing "implementation" with "integration" resulted in only 37 matches and none of the search results were considered applicable.

Using Google search for the words "LIS" or "LIMS" and even their full extended versions produced a lot of search results containing fairly general information regarding the words. Using Google Scholar generated more relevant studies as might expect. However again adding the words "implementation" or "integration" seemed to produce more interesting search results on both engines. Playing

around with the key words and adjacent words helped in finding appropriate material and ended in useful material being found during most of the steps. Reviewing material which might have not been the most useful for this thesis could lead to more significant studies via its references. This sort of search engine rabbit hole found many interesting studies and digitals to refer to on this thesis.

Due to the large number of studies and digitals presented through the different searches it is somewhat cumbersome if not difficult to find relevant material about LIS. In the end picking the studies for topics like benefits and features of LIS and different sort of implementation and integration guides was fairly straightforward. There were many studies found in these categories and it was just a matter of personal decision. In many cases the material chosen for reference had something that made them stand out. This might have been exceptionally well curated text which made it practical to search for the relevant information. Or maybe the study had certain visual appeal to it e.g. well demonstrated and easy-to-understand images and figures. There probably would have been many more excellent studies to choose from for reference. The principal documents selected for the review are listed on table 3. The aim of the review is to answer research questions 1. and 2. The review applies the method presented by Torres-Carrión et al. for systematic literature review: planning, conducting and reporting a review. [14]

Table 3. Literature chosen for review.

Document reference	Document title	Main topic
[2]	LIMS: Implementation and Management	Comprehensive guide to LIS.
[4]	LIMS-järjestelmien kehittäminen akkreditoidun kliinisen kemian laboratorion tarpeisiin	Main features of LIS and clinical laboratories including standards and quality systems.
[5]	Laboratory Information Systems Project Management: A Guidebook for International Implementations	Complete guide for LIS in general and LIS integration and implementation projects
[6]	Laboratory Information Management Systems in the Work of the Analytical Laboratory	LIS functions in clinical environment.
[8]	Laboratory Information System (LIS)	General article on LIS.
[10]	A Look At Laboratory Information Management Systems	Article on features of LIS.
[11]	Benefits of Integrating Your Laboratory With a Laboratory information Management System (LIMS)	Article on LIS benefits.
[12]	Implementing LIMS: A “How-To” Guide	A how-to guide for LIS implementation.
[16]	Laboratory Data and Integrated Laboratory Information Systems - Implementation Guidance	Detailed guide for LIS implementation.

To answer research questions 1. and 2. the background literature should find answers for improvements in laboratory workflow by reducing manual labour and short-term/long-term effects of LIS integration versus non-integration. Studies [2] [4] and [6] worked as a solid base in understanding LIS. The studies share light to the history of LIS e.g. how the systems have developed and describe the elements of LIS starting from the basics and building up to give a comprehensive idea of how LIS relates to other laboratory functions. The different authors have their own ideas how to define LIS and they share these ideas on the studies.

Reference [2] was chosen for its very comprehensive and detailed focus on explaining LIS and everything relating to the system. The author goes into great detail in analysing LIS for the reader. The historical part of the study in addition to basic history of the systems also presents different case studies of system implementations in different companies. These case studies suggest substantial labour savings and benefits from LIS implementation.

The different companies and the improvements are as follows:

- Ralston Purina Company: 15 to 20 years of estimated labour effort savings per year.
- Mobil Research and Development Corporation: Increased productivity around 64% between 1969-1983 with 25% increase in workload with decrease of 15 laboratory technicians.
- Calgon Water Management: Overall productivity increased by 30%.
- Construction Technology Laboratories Inc.: 2/3 of testing paper work automated with estimated 500 technician work hours saved annually.
- Eastman Kodak Company: Reductions in cycle time and errors, increased operation efficiency, enhancements in manufacturing and customer service.
- Miles Inc.: Laboratory quality control documentation provides higher customer satisfaction and laboratory result credibility. [2, p.6-8]

In the study [2] by Nagawa presents that LIS can improve the performance, efficiency and capabilities of a laboratory and the case studies seem to support these claims. So it can be proposed that laboratory automation improves laboratory workflow by increasing productivity while reducing unnecessary manual labour thus freeing laboratory technicians to concentrate on other laboratory work. The case studies speak in favour of the long-term financial effects, productivity improving and labour reducing effects of LIS integration versus non-integration.

Study [4] by Kuokkanen presents general idea of LIS, history of the systems, many features and other applicable information regarding the systems and clinical chemistry. A case study by LabWare mentioned on the study [4] suggest the greatest advantages of LIS according to users. These are fast search of archived data, better quality of results via instrument interface, versatile reporting and uploading of sample results in real time. From these advantages at least archiving, reporting and uploading results can be said to lessen manual labour in the form of negating manual typing. Manual typing is slow, cumbersome and exposes for human errors so by reducing it the laboratory workflow should improve and free technicians for other tasks. Laboratory management may then allocate work accordingly creating efficiency in workflow. The reducing of manual labour can be considered as a short-term

effect of LIS integration versus non-integration. Once the system is installed there will be a gradual decrease in paper work.

The focus of study [6] by Skobelev et al. is on the common traits and functions of LIS in clinical environment. This study also underlines the need to reduce errors caused by the human factor in laboratories and suggest that report generation is one of the most important functions of LIS. Some other functions mentioned in relation to workflow improvements are input of data and results, enrolment of samples, flexibility and adaptability and verification/validation. The study summarises that LIS is the optimal tool with the flexibility to increase the efficiency and quality of research. Again for the users convenience it is the automation of LIS with beneficial features like electronic reporting that makes it invaluable for users. But it can also be pointed out that the systems flexibility is one of the key factors in reducing unnecessary labour to improve workflow. Short- and long-term effects of integration seems also to be related to automated tasks reducing manual labour here when compared to non-integration.

The digitals [5] [12] [16] focus more on the implementation and integration side of LIS and go into detail regarding this topic. Digital [5] by APHL also presents good basic information of LIS. Digital [16] also by APHL builds on digital [5] and goes more into detail of LIS implementation. However the digitals also list LIS benefits. According to digital [5] LIS improves and provides better quality control and assurance by providing laboratories with a tool that assembles, analyses and manages data. This is highlighted by improved efficiency, quality and reporting by precise and thorough delivery of data for the users. Digital [12] by Avery et al. lists improved effectiveness and efficiency as long-term payoffs for LIS implementation. Avery et al. describe how their laboratory has gone through three different LIS implementation processes. In the end despite some adversity the implementations provided them with quality data while being time efficient, cost-effective and significant in enhancing the business side of the laboratory. On digital [16] having integrated LIS is said to save time and reduce the human error. By the system being accurate, timely and having information available for

professionals electronically the risk of manual mistakes is minimised. This translates to better care for patients and the overall management of healthcare. So digitals [5] [12] [16] seem to agree on the benefits of LIS on improving laboratory workflow. This is achieved by increased efficiency and quality control, precise reporting and by being more cost-effective all while reducing manual labour. These are either short- or long-term effects of integration.

The digitals [8] [10] [11] share more general information regarding LIS explaining basic functions, features, benefits and system architecture. Salleh describes on digital [8] how LIS are designed to be advantageous of computerisation and information technology (IT) in order to automate reporting and testing which are integral capabilities of the systems. Salleh confirms that automation is a key element in modern laboratory workflow which can be considered as a manual labour reducing aspect. Digital [10] by Damoulakis highlights LIS' adaptability: the systems are capable of supporting different laboratory types, streamline laboratory operations improving efficiency and productivity and work as the backbone of laboratory work. Automation helps to overcome data management by the laboratory personnel thus reducing human error to boost productivity and efficiency. A key component of LIS that Damoulakis points out for an efficient laboratory work is sample tracking for significant reduction of errors and loss of data. These are time saving and efficiency improving qualities. Other significant benefits for efficient, productive and quality workflow mentioned on digital [10] are cost savings from minimising manual tasks and scalability of the systems to increase sampling volume without significant increase of workload. These are substantial benefits that talk in favour of LIS how the system integration reduces manual labour in laboratories. Digital [11] by CloudLIMS mentions LIS integration as having qualities to eliminate transcriptional errors caused by manual entry of data, reduced TAT by automated and streamlined workflow, boosting predictive analysis and increase profitability. These are qualities to reduce human error, increase operational efficiency and productivity, eliminate issues proactively and save time and money as well. Once again there seems to be similarities

between the short- and long-term effects of LIS integration in comparison to non-integrated laboratories.

All in all there seems to be a consensus among the studies and digitals that laboratory automation is a major factor for streamlining laboratory workflow. Many aspects seems to speak on the behalf of that integration improves laboratory workflow and reduces manual labour and that there are considerable short- and long-term effects from LIS integration. All the studies agree that LIS improves efficiency in laboratories. This increased efficiency has effect on manual labour in the form of reducing manual data management and errors caused by manual work, cost savings of minimising manual tasks and thus saving time overall and freeing technicians for other tasks improving effectiveness. Four out of nine studies agree on cost savings of LIS implementation through different aspects like improved efficiency and effectiveness, labour savings and productivity boosts. Thus financial benefits could be count as another improvement of LIS integration that reduces manual labour without compromising productivity. Overall LIS seem to have many desirable elements and features that reduce manual labour and improve workflow in laboratories either in short-term or long-term. The systems flexibility makes it adaptable and attractive for many different laboratory environments.

4 LIS Integration and Implementation Process

LIS architecture consists of computer HW and SW. This chapter details how these components relate to the deployment process of LIS integration. Figure 6 presents this architecture. Also details about LIS integration approval process is covered in this chapter.

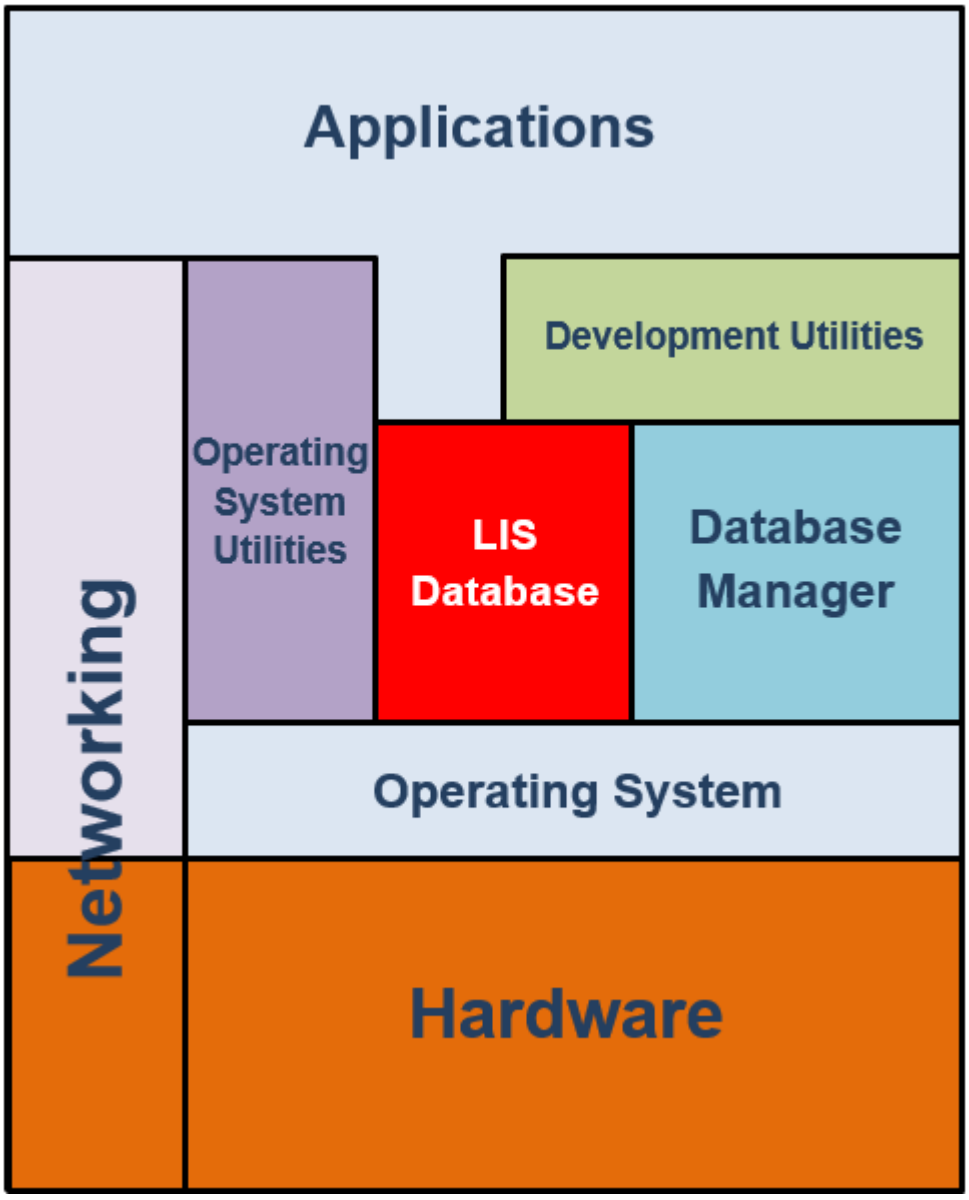

Figure 6. Hardware and software architecture of LIS. [2, p.21]

Skobelev et al. propose that:

> “Integration of laboratory information management systems with the enterprise’s information systems will make it possible to promptly transmit required data to the laboratory and the enterprise administration.” [6]

LIS should fulfil the following requirements: system connectable to an instrument, keep track of reagent consumption and dilutions, handle calculation formulas used in stabilisation and ability to handle statistics. Integral part of LIS integration is connection to clinical information system (CIS) in order to receive orders and patient information database to convey results. For this reason it is important that the different systems are integrated from the beginning or during implementation. The current data transport intermediary language for LIS is Health Level 7 (HL7) which allows the interchangeability of data. Due to updates on HL7, the different systems and instruments interfacing them all may prove to be a challenging task. Together with HL7 other commonly used industry data standards are Logical Observation Identifiers Names and Codes (LOINC) for identifying laboratory observations, Systemized Nomenclature of Medicine (SNOMED) which is a standard for medical terms and International Classification of Diseases-10 (ICD-10), the international codes for medical diagnoses and procedures. [4, p.10] [5, p.68] [8]

4.1 Hardware Devices

HW include devices such computer, storage devices, input devices and printers. Computer works as the control centre of the whole system. As the control centre it controls the functions of all the system elements: HW, SW and networking. Storage devices as the name suggest save data and programs. Data may be saved in several different ways such as on disc drives, optical drives and flash drives and they all have their own features. Input devices function as a mean to get information to the computer. Such devices are, for example, computer screen, keyboard, barcode reader and scanner. They all have their own way of inputting and displaying data. Barcode readers are

especially useful for scanning sample tubes and act as a mean to send the patient information on the sample tube to the computer. Printers are useful for different printing procedures like specific sticker printers for printing stickers containing patient data (including barcode) for sample tubes and more conventional printers for printing out analytic results etc. Besides the typical devices LIS are also connected to a wide variety of different clinical instruments. These specialised devices include but are not limited to PCR analysers, extractor instruments and DNA sequencers. The most sophisticated instruments are capable of reading sample IDs from sample tubes, sending an inquiry to LIS regarding the test to which the LIS answers what to with the test. This is the so called bi-directional connection. [2, p.21-23] [4, p.14-15]

> “Hardware performance improvements have facilitated the use and acceptance of increasingly sophisticated and easy to use software. Relevance of the newer hardware to your needs should be considered relative to the availability of the software capable of meeting those needs.” [2, p.85]

As explained the HW components of LIS consist mostly of typical devices related to composing a data base architecture. Exception to normal LIS architecture are systems used in the pharmaceutical market. These systems are specialised in stability testing and as an add-on to their LIS the pharmaceutical companies want to include stability-testing modules. For the system to work efficiently the server needs to be robust with sufficient memory so as to be fast and reliable. Insufficient servers cause lag in data transactions deeming the system unreliable. As with many other devices in healthcare the LIS servers should be protected with uninterruptable power supply (UPS) and proper backup systems for data. [12]

4.2 Communication Devices and Software

Communication devices include such simple components as cables that connect all the different devices and act as a pathway for data transfer. Networking HW include switches, protocol translators and multiplexors and they tie different computer systems together. Data connectivity between instruments and LIS is established with interfacing HW such as digitizers, signal filters and

instrument controllers. For designing and planning LIS interfaces there exists specific ready-to-use tools like LimsLink. Systems like LimsLink aim for a total laboratory integration by interfacing every system in the laboratory from LIS to instruments and informatics systems all the way to ERP and scientific data management systems (SDMS). [2, p.23-24] [4, p.15] [15]

> “For a laboratory, networks facilitate the movement of data between instruments, the LIMS, and other corporate information systems.” [2, p.85]

SW include programs like operating system, database, applications, networking and utilities. LIS application is used to provide actions like sample log in, sample tracking, test scheduling, test data entry, test approval and reporting. These actions differ between different LIS applications. Utilities may be used for developing and maintaining LIS applications. It is good to keep in mind that LIS SW are specifically designed for laboratories. The LIS SW installation is the decisive point of any LIS project as once the system has been installed and configured it is ready for use. [2, p.24] [5, p.88] [16, p.5]

4.3 Approval Process

LIS integration needs to go through comprehensive approval process which varies in complexity from organisation to another. The approval needs to take in account many aspects like system cost including HW and SW, laboratory operation cost, size and number of laboratories and organisational customs. Main points to take into consideration when choosing a LIS are the quality of the system, that it fulfils the requirements of the customer, user-friendliness of the system and a supply agreement that satisfies each party. [2, p.138] [4, p.9]

> “A laboratory must devote the necessary time and resources to planning, selecting, and implementing a new system.” [12]

Good practice would be to complete a survey of LIS technologies and review implementations of past cases in similar laboratories. A site visit would be preferred to discuss the implementation and use of the system in formerly integrated laboratories. This helps in mapping the potential features, setbacks

and costs of the system. There are three ways to implement LIS: the system is created from scratch, by acquiring an existing system or by acquiring an existing system and modifying it to meet the requirements of the laboratory. There are over 100 LIS available on the market so determining the right system for the laboratory may be cumbersome. Thus dialog with different vendors is advisable to map out the most potential system candidates. Creating a system in-house has the advantage of meeting exactly the specifications wanted by the laboratory. Developing custom systems is expensive, time consuming and needs extensive testing and validation. For this reason custom LIS cannot be recommended for smaller laboratories. In the end it has to be determined if the LIS implementation with its costs and requirements is worth the effort. [2, p.147] [4, p.7] [12]

After the mapping for the approval is finished the implementation and operating costs for the LIS needs to be determined. For this comparative analysis of the LIS' costs and benefits are calculated through a financial business case. Justification for LIS is then completed through preliminary review approved by management and it is determined whether further analysis is needed and who else needs to be involved in the approval process. Lastly the approval needs to be obtained from the designated individuals or groups. [2, p.147]

4.4 Implementing LIS Integration

Before implementing LIS data migration should be possible from the old system to the new. This data could be on a hard drive or in a data base. When implementing LIS it is important to include database management system (DBMS) as this SW controls data creation, storing, management and protection. DBMS helps sharing data between different users and programs. This is convenient when there are many individuals and groups creating and analysing data on the system. Relational database management system (RDBMS) is a flexible, unconstrained system that helps reorganize data in number of ways unlike normal DBMS. RDBMS utilise Structured Query Language (SQL) which is a standardised information working approach. RDBMS may require additional

configuration of the HW and database of the system. Multimedia databases are able to handle more complex data like pictures and sound unlike DBMS or RDBMS that primarily deal numeric and textual data. This also demands higher system performance capabilities from multimedia database. [2, p.83-84] [6]

LIS should enable the use of normal computer environments like Windows, Microsoft Office and Excel including their SW products for accessing databases like Microsoft Access, SQL and so on. LIS implementation should take in account and conform system security relating to users like data identification, acquisition, indexing, access, storage and maintaining data confidentiality. Thus the system should be password protected to prevent unauthorised access and different user authority levels should be implemented. [6]

For the implementation to be successful the laboratory has to review certain parameters:

- Number of simultaneous users
- Annual number of sample and analysis result documents
- Number of logged documents online
- Requirements for archiving reports
- Type of reports required
- External load of applications on the system unrelated to LIS. [6]

There are three essential aspects to a high quality LIS. Firstly the system ought to be dynamic and able to direct the sample run throughout the process. This includes automated work processes in real time like automated work requests, printing reports and worklists, distribution of workload, controlling device interface, approving and validation of results. Secondly the user interface needs to be unambiguous, user friendly and easy to learn. Colours should be utilised to differentiate functions from each other, information should be shareable with ease and the system should be open for improvements. Thirdly the system has to be connectable to instruments within the laboratory and other systems. These are, for example, patience databases, accounting systems and reporting systems. Interoperability is hardly a simple task when it comes to LIS as

different systems speak their own language and differ in the storage of data. For this reason the vendors need to determine the technical details on how to operate the systems together. Having understanding of concepts like types of interoperability, system integration options, standards and integration tools are essential for LIS integration. [4, p.10] [16, p.10]

What makes LIS implementation special is its role in healthcare. The laboratory data provided by LIS is transformable to valuable information for disease surveillance, prevention and treatment. Laboratory data is fundamental for integrated disease surveillance and LIS plays a significant role in collecting individual data for mapping out disease among population. The data is useful for determining better health goals for the public. [16, p.6]

Most LIS are implemented so that the database is in the client server and the graphical user interface (GUI) is on the client HW which allows data processing on the client server. Software-as-a-Service (SaaS) systems are becoming more popular though. These systems are cloud-based and are executed on demand meaning that no SW or HW are needed on customer site other than a pc connected to the internet. [6]

LIS implementation work is possible to breakdown into smaller segments for ease of management. These segments produce concrete results and are complete once all accompanying products are finished successfully. LIS projects typically consist of many phases like defying requirements, functional description, technical description, implementation, testing, deployment and maintenance. Different work products and subprojects initially compose the whole implementation process. LIS implementation work breakdown structure is visualised on Figure 7. [2, p.121] [4, p.8]

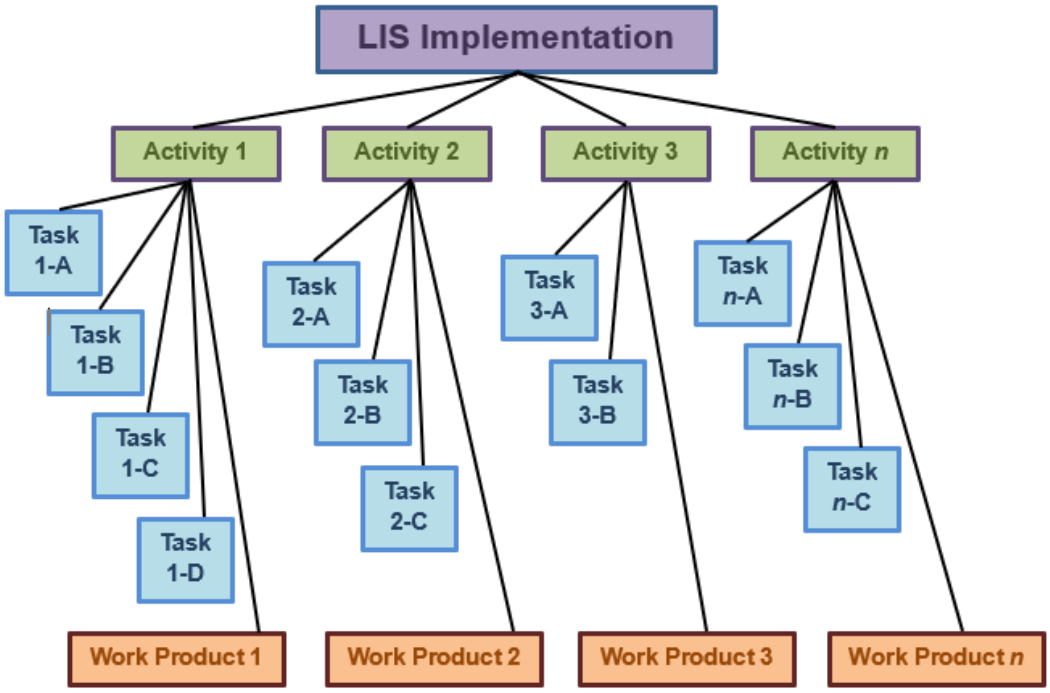

Figure 7. Work breakdown structure of LIS implementation. [2, p.122]

Aspects that may affect implementation of LIS successfully may include failures in identifying goals, staff involvement, management, planning, lack of resources and the overall execution of the LIS project. Failures in LIS projects are rarely caused by the actual technology or product but rather the organising and execution of the project is to blame. Thus it is important to have well defined goals and business objectives for the project that take into consideration the needs of the laboratory and its workers throughout the whole process. LIS implementation may surface inefficiencies in the internal routines of the laboratory. The system should not be built around to support these routines but rather the issues should be dealt with by improving the internal processes. During implementation it is important to follow industry qualification standards in case the laboratory is under such accreditation. Having to follow the standards and accreditation of healthcare industry is one of the characteristics of LIS projects. Standardisation allows data structuring from multiple sources routinely and is applicable for processes, tools and data. LIS standardisation covers test names, specimen types, electronic messaging and test orders. [2, p.88-89] [4, p.6, 8 & 14] [16, p.13]

After the LIS installation some configuration issues may arise and it is vital for system stability to handle them. Such tasks as populating data dictionaries, designing reports, configuring interfaces and system testing need to be performed to ensure proper system functions. This can be time consuming as the laboratory needs to define many things like sample types, test protocols, diagnostic instruments and user ID’s with relating passwords etc. The system should be designed in a flexible manner and be as transparent as possible for the user. The ability to customise the system by the user is one of the more important features of modern LIS. Feedback from the users and laboratory process information is important to be reviewed. This should then be discussed with the LIS vendor for any potential improvements to be made. [4, p.12] [12]

In order to visualise the whole LIS implementation process Gantt chart may be used to help in planning the project when divided into different activities. This may assist in scheduling labour resources accordingly without the danger of over or under working personnel. However even the most well planned projects may encounter unforeseen setbacks and interferences. With careful planning the project schedule is easier to predict. When issues do occur the management has to be active and committed in dealing with any disputes that may surface. Here’s an example of a Gantt chart in the context of LIS implementation. [2, p.124] [12]

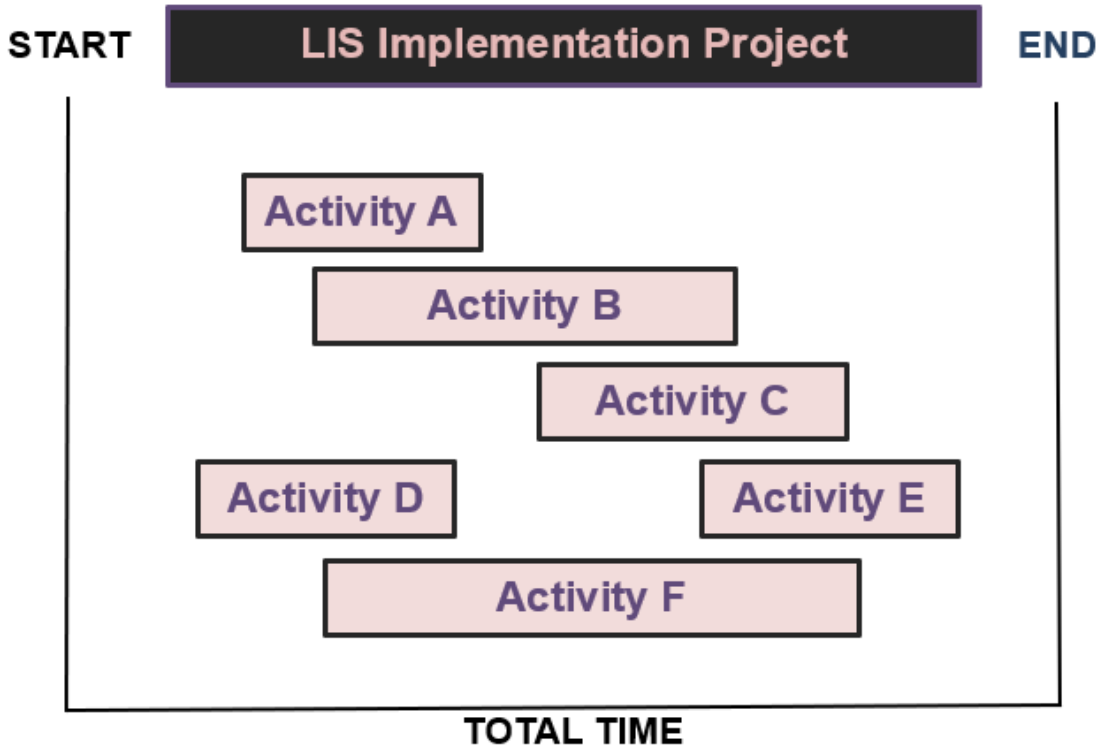

Figure 8. Gantt chart of LIS project broken up into different activities. [2, p.124]

LIS projects involve resources from several fields of expertise as depicted on Figure 9 from personnel within and outside the organisation. Key groups during implementation are project management who lead the project, LIS technical working group and representatives from HW and application vendors. The essential groups of personnel should be identified and then the individual personnel within the group. Well organised project structure ensues effective communication including stakeholders helping the project to evolve. [2, p.124] [5, p.35 & 69]

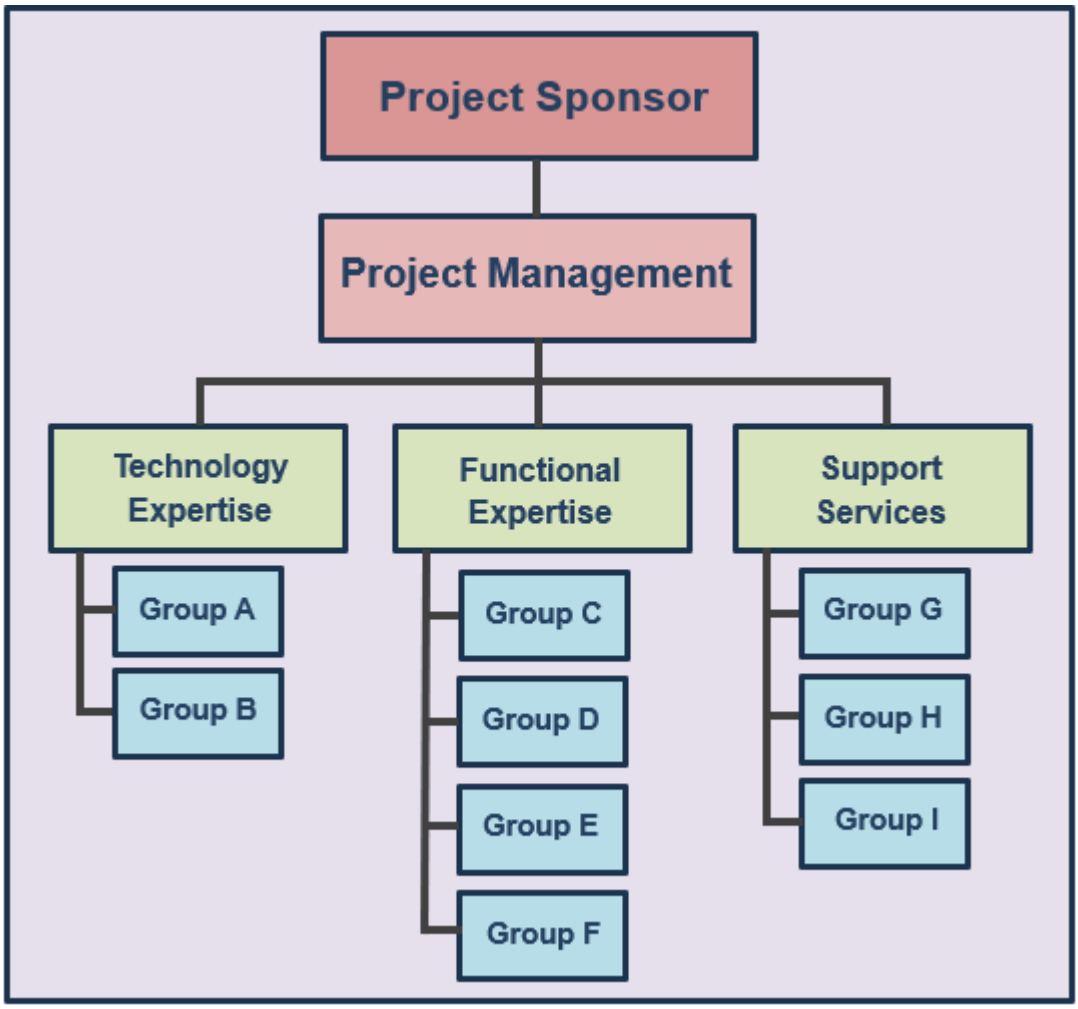

Figure 9. Overview of a typical LIS project organisation. [2, p.125]

Some personnel may only be involved in the project part-time but depending on the size of the project some personnel are required to work full time with the implementation. The project dictates the labour needed from each individual. Involvement may include personnel from different laboratory groups, sales, legal department, IT support and HW service. Difficulties lie in how to get all the different individuals, groups and teams of specialists to work efficiently together for the project to finish successfully. [2, p.125]

LIS are not stationary but are subjected to constant improvement and development. This means that in order to secure the investment put into the implementation of the system it is important to have post-implementation support. In order to maintain post-implementation support applicable personnel,

tools, funding and procedures are needed. It is also relevant for the laboratory management to maintain their commitment throughout the system lifecycle. With this kind of infrastructure the laboratory ensures that the system serves their interest with reliability and predictability in mind. The following Figure 10 visualises the different stages of laboratory information system lifetime cycle. [2, p.166] [12]

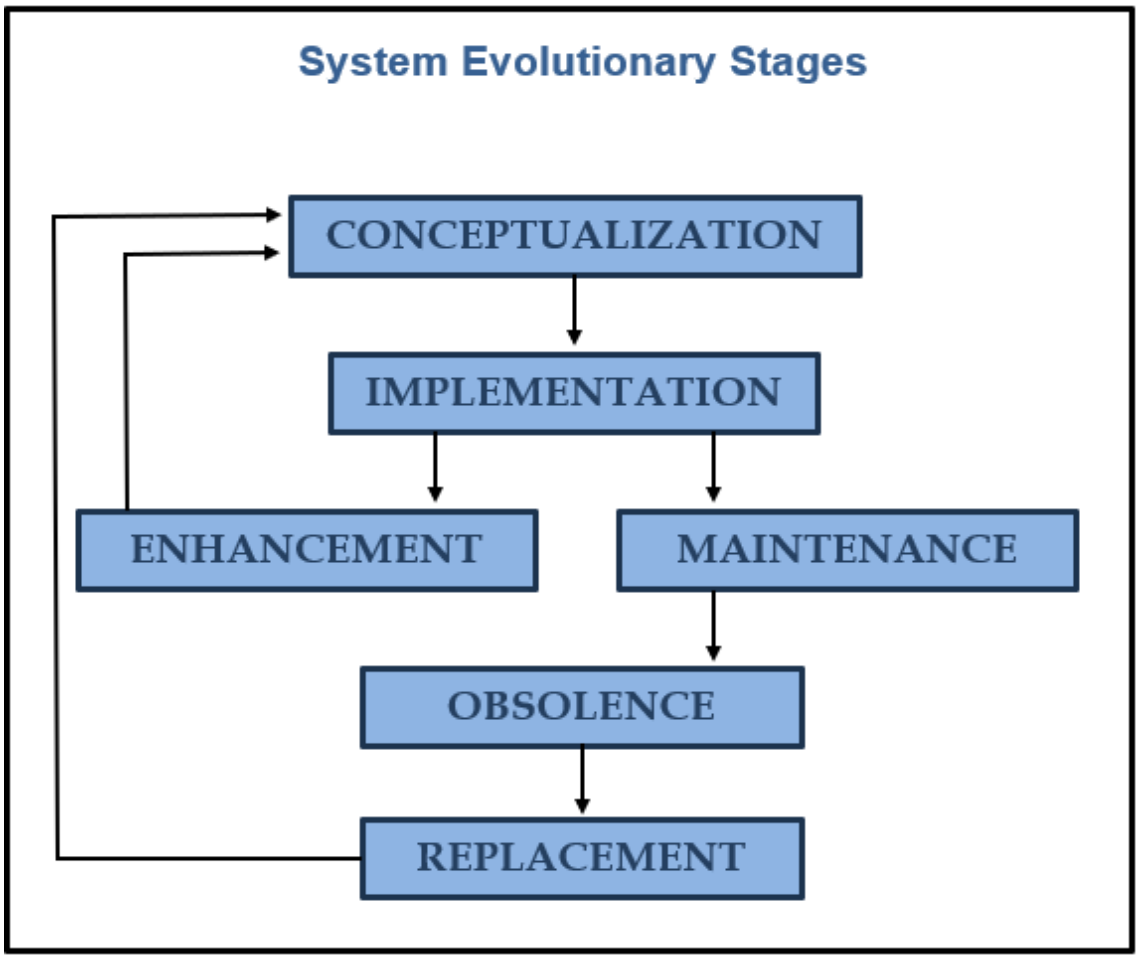

Figure 10. Lifetime cycle of a LIS. [2, p.167]

As the above figure suggest there will always become the time when LIS becomes obsolete and needs to partially or totally replaced. Reasons for this may be that the technology becomes outdated thus maintaining and/or enhancing the system becomes inconvenient. These two levels of obsolescence in LIS are called technical and functional obsolescence. Technical obsolescence occurs when the HW or SW becomes outdated and

functional obsolescence occurs when the system becomes unreliable due to becoming costly, difficult to use or lack of support. For the organisation using the laboratory information system it is important to track the development of LIS technologies in order to prepare for the inevitable replacement or upgrade of the system. However great consideration, critical assessment and examining recent cases should be applied during any transition period to new systems. [2, p.174-175]

4.5 Recommendations for LIS Implementation

This section sums up important aspects of LIS implementation and integration. Based on the material presented earlier in chapter 4. these recommendations are only suggestive and portray the authors view for any potential LIS implementation and integration project to succeed. Thus the suggestions might not go one to one with each individual LIS project. The recommendations have been split into themes by technical elements and project related aspects. Table 4. Below focuses on recommendations based on their technical aspects.

Table 4. Recommendations for the technical aspects of a LIS implementation.

Recommendation	**Explanation**
Data migration from the old system to the new system	Before any actions regarding implementation are made all important data should be saved for data migration from the old system to the new system. This secures data integrity.
Connection to CIS	For LIS to receive test orders and patient information for conveying results it is integral to have connection set up between LIS and CIS.
LIS should work in normal computer environments	LIS should understand or be compatible with SW like Linux, Microsoft (MS) Windows, MS Office and Excel including database management like MS Access and SQL etc.
LIS should be data secure	Data security of LIS implementation takes into consideration user security like data identification, access to the system, data storage and data confidentiality etc.
Connectable to instruments	LIS should be connectable to a wide variety of clinical instruments and other applicable devices. It is of importance that the systems are integrated from the beginning of the implementation.
LIS should track laboratory records	LIS should be able to handle statistics and calculation formulas, keep track of reagent consumption and dilutions etc.
Use ready-to-use tools for LIS interfacing	To ease the planning and designing of the interfacing of LIS to other systems and instruments it is advisable to use specific tools made for this purpose.
Implement industry data standards	LIS should use standard data exchange formats like HL7, LOINC, SNOMED, ICD-10 etc. for data integrity and if the laboratory is under accreditation.
Robust server	LIS server has to have enough robustness and sufficient memory in order to be fast and reliable.
System protected with UPS	LIS system should be protected with UPS for potential power outages.
Thorough configuration of LIS after installation	LIS should be configured for the vitality of system stability. This ensures proper system functions through system testing, interface configuration and report designing etc.
Flexibility of LIS	Flexibility makes the system user friendly. Users should be able to customise the system for their needs.

The following table 5. represents the organisational recommendations for a LIS implementation project. The table points out important things to note for LIS project managers and organisations and how to succeed in such a project.

Table 5. Recommendations for the project organisation of a LIS implementation.

Recommendation	**Explanation**
Approval process	Before the LIS integration a comprehensive approval process is conducted taking account system cost, lab operation cost, size and number, organisational customs etc.
Review past implementations	In order to map out the project it is good to review past LIS projects.
Survey LIS technologies	It is good practice to get familiar with different LIS options available. System should be of good quality to satisfy the parties involved.
Identify inefficiencies	It is important to deal with inefficiencies in internal routines before LIS is implemented. LIS is not implemented to deal with these.
Choose the correct LIS implementation	There are three ways to implement LIS: Creating the system from scratch, acquiring an existing system or modifying and existing system.
Consider the three essential aspects of a high quality LIS	The system should be dynamic, user friendly and interconnectable.
Conduct a comparative cost analysis	To estimate the cost of the system and to justify the LIS implementation a cost analysis is advisable.
Review certain parameters	Successful implementation takes into account the number of system users, number of samples and the number of documents/data created.
Breakdown the project into segments	For ease of management the project work should be divided into smaller segments e.g. definition of requirements, functions and technical aspects, implementation, testing, deployment, maintenance etc.
Be aware of negative effects	Negative aspects during implementation may include failures with staff or management involvement, planning, goal identification and lack of resources etc.
Recognise key resources	Key groups during the LIS implementation are project management, technical LIS specialists, HW specialists and the LIS vendor(s).
Efficient interoperability of different work groups.	Many professionals from different fields (e.g. lab techs, sales, legal staff, IT & HW support etc.) are involved in LIS implementation projects. The key is to get the groups to work efficiently together.
Keep in mind the decisive point of the project	Once the LIS SW is installed and configured the system is ready for use.
Have a clear goal	Well defined goals and business objectives help the project to succeed and makes it easier to deal with issues.
Remember post-implementation	LIS are under constant improvement and development and thus require regular maintenance. It is good to keep in mind that like any system also LIS need to be upgraded or replaced at some point.

This chapter can be concluded in underlining LIS' special role in healthcare work and laboratory automation. On top of being a seminal tool for laboratories, all the data and information gathered from LIS operations is invaluable information for disease control, treatment and research.

5 Practical Methods

There were different methods used during this thesis in addition to literature research which were or were meant to be as follows:

- Time-motion studies (cancelled)
- Cost benefit calculations (cancelled)
- Surveys
- Interviews
- Analysis

5.1 Time-motion Studies and Cost Benefit Calculations

Originally the main research methods for the thesis were to be time and motion studies and cost benefit calculations. As time and motion studies focus on the analysis of repetitive tasks performed by a person and the time needed to do so the method fits perfectly for the analysis of laboratory workflow. Laboratory work often include repetitive tasks especially in high input clinical laboratories. With the information received from time and motion studies it could have been determined what processes are efficient and which unnecessary processes should be replaced with others. Deepening knowledge of these research methods were of essence for the project to be successfully finished. This research would have been invaluable to document for the concrete data how LIS integration would benefit the customer and the company alike. [7]

In order to conduct a time and motion study one needs to “break down a task into a set of work elements” to better understand how the task works. After this the amount of time required for each work element would have been measured. This can be established by measuring the average for each work element over several cycles. Then it would have been determined if there is a need to add an allowance to the average time for breaks and shift changes. [7]

> “A cost-benefit analysis is a systematic process that businesses use to analyse which decisions to make and which to forgo.” [17]

Cost-benefit analysis is a method that concludes potential benefits that are expected from situations or actions and then deducts the total costs from having done those actions. So in a nutshell it sums up the benefits of making a decision or taking action minus the cost related to that action. The method involves measurable financial metrics like earned revenue, saved costs etc. The analysis may include abstract benefits like employee morale or customer satisfaction and more complex analysis may incorporate sensitivity analysis, cashflow discounts, what-if scenarios and so on. All in all an analysis that produces more benefits than costs can be considered favourable. [7]

According to different studies the economic impact of LIS integration is substantial. Articles from Journal of Medical Systems regarding cost justification and cost analysis present tangible and intangible benefits in pre and post implementation comparison. [18] Despite the systems being expensive to build, install and maintain the tangible benefits over four years of operation included $115,327 yearly savings. Article from American Journal of Clinical Pathology regarding impacts of computerised systems in clinical laboratory over the course of seven years adds to the tangible benefits by showing that there is a relation between successful implementation of management systems and laboratory costs. [19] Cost analysis from Clinics in Laboratory Medicine mentions tangible financial advantages provided by long-term experience of laboratory automation. [20] Trends also point to further improvements in cost effectiveness for LIS. Intangible benefits included considerable impact on many departments and clinical services and there is acceptance for intangible benefits of laboratory computerisation. While some of the studies not being the most recent ones they still mirror the financial benefits caused by LIS implementation as the basics of the systems have not changed over the years. [21]

5.2 Survey

Survey was conducted to gather mass data of information regarding LIS. The survey was sent to laboratories of different sizes ranging from large municipal diagnostic laboratories to smaller private research laboratories and everything

in between. The questions took rather simple and basic approach to the subject. The survey respondents varied and cut through the different levels of laboratory personnel from laboratory technicians to laboratory supervisors. Each individual were answering from their own work related perspective. As a survey it cannot be determined what were the conditions in which the respondents answered from and what were the respondents views towards the survey. The answers were documented and later analysed keeping in mind the best possible unbiased scientific practices. Analysis of the survey answers were later used for conclusions to map positives and negatives in addition to personal thoughts regarding the method. Next section lists the survey questions translated from Finnish to English.

Survey questions:

- Is LIS in use in the laboratory? If yes, what kind of system is it? If not, what are the reasons for this?
- How does LIS serve the everyday laboratory work? How could LIS benefit the laboratory if there is no LIS in operation?
- What are the best features affiliated to LIS?
- What are common issues related to LIS? Or what the issues could be if LIS is not in use in the laboratory?
- What kind of data does/would the LIS handle in the laboratory?
- What kind of features are LIS lacking?
- Is there anything else you would like to mention regarding LIS?

Surveys work well as a tool to determine user opinions of a large group and surveys may reveal interesting patterns within the scope groups. Surveys ought to be composed carefully in order to target the right audience and to avoid failure. Failures may occur from asking incorrect questions from incorrect target groups resulting in poor data. Surveys can be conducted any time depending on the scope of the survey and the size and structure of the survey depend on what is the wanted end product. Having an idea what to accomplish while composing a survey is beneficial in order to achieve satisfactory results. In addition to having a clear goal, also crucial is having constructed a clear

schedule for the survey. Sufficient time and well composed survey guarantee successful research data. [22, p.327-330]

5.3 Interview

Besides the survey the main core of the data collection to conduct this study was through interview. Due to practical reasons interview was conducted via a video call. This method not just enabled the easy recording of the interview material for later documentation and transcription but helped in interviewing persons that were remote from my location as well. Interviews have the quality of introducing more in depth perspective for the topic at hand. It also lets the interviewee better share light on their own views and personality. Thus interview as a method is more intimate than a plain survey. Goodman & Kuniavsky summarises interview as follows:

> “Observation is critical, but to really know the user’s experience, you have to ask him or her about it, and that’s an interview.” [22, p.129]

The interview is cross-cutting through the different layers of laboratory workflow, from the manual workers all the way to the decision makers. This way the benefits can be seen from all the different angles of the organizations working with LIS. Once the actual research interview data was collected then it was subjected to analysis for the final results having in mind applicable scientific practices.

Following is a list of some of the key words/topics that popped up during the interview:

- Laboratory Information System (LIS)
- Integration process
- Laboratory workflow
- Customer perspective
- Time motion study
- Cross benefit calculation
- Integration versus non-integration

To achieve neutral position the interviewer needs to be unbiased. This is done to position yourself away from your product. This helps in receiving the interview material whether it is positive or negative and understanding the interviewees perspectives. Nondirected, neutral questions make interviews more natural helping in analysis and getting unbiased answers thus creating better results. [22, p.131-132]

Interviews follow basic structure which start with basic questions that lead to more detailed questions followed by the bigger picture and lastly conclusion that summarises the interview. This structure is generally divided to six sections:

- Introduction
- Warm-up
- General issues
- Deep focus
- Retrospective
- Wrap-up [22, p.129-130]

The interview structure was utilised to conduct the interview questions. The structure helped in grouping the different questions. This was useful to form the relation between the questions to each other. It also assisted in changing the perspective from question to question. Without the help of the structure the interview template would have been shorter or narrower. All in all the structure made it easier to think of different things to ask and what to ask but also helped

in choosing the angle for each question. Next section lists the interview questions translated from Finnish to English.

Interview questions:

- Could you introduce yourself and your background?
- How is you educational background related to LIS?
- How does your work relate to LIS?
- What are the existing LIS solutions?
- What are your experiences on LIS?
- What is the common opinion towards LIS nowadays?
- What is expected of the system?
- How does LIS serve everyday laboratory work?
- What kind of data is commonly handled by LIS in laboratories?
- What beneficial features are related to LIS?
- What are common issues faced by LIS?
- What are possible issues with LIS?
- How has LIS changed laboratory work?
- How has LIS changed your work?
- What kind of new features would be welcome on LIS?
- How would these features benefit those that work with LIS?
- Is there anything else you would like to mention regarding LIS?

6 Analysis

6.1 Analysis of Surveys

Due to the amount of survey answers received the scope of the survey is narrow. The analysis of the survey answers will follow the question structure of the survey. All the customers have an operating LIS so the answers have the perspective of LIS users with varying backgrounds. The analysis aims to describe the exact views of the customers from the survey precisely as they were written down and agreed in advance for it is important not to make any mistakes. The author ponders the answers and comments or makes suggestions for possible improvements based on what was said.

The different customer laboratories have varying types of LIS. The answers to how specifically they would describe their systems varied as well. The first system in use by customer #1 is the bi-directional Clarity LIMS by Illumina which covers the whole workflow of the laboratory including the partly integration of their laboratory instruments. Since no other specifications were given it is assumed that here the customer has acquired an existing system with no substantial modifications. The second system used by customer #2 is the bi-directional LabVantage 8 from LabVantage Group which has been configured by Whitelake Software Point. Here we can see the approach of the customer acquiring an existing system from a LIS vendor to be configured by LIS solution specialists to meet the customers preferred definitions. The customer has nicknamed their system as “the Wizard”. The last system used by customer #3 is only said to be a bi-directional LIS so not much else can be said about their set up other than that they have the benefits of the bi-directional interface. [23] [24]

The different ways that LIS serves the customers is presented on this paragraph. For customer #1 the system monitors daily work and performs clinical supervision. The tracking of singular samples, sample sets, laboratory personnel, instruments and reagent lots also belong under LIS’ supervision. The

LIS also saves the sample results. These are your typical LIS functions and perhaps one way to improve the LIS usage would be to integrate all remaining unintegrated instruments to their LIS. Customer #2 explains that their “Wizard” is an information management system which controls laboratory actions from research requests to producing laboratory results. “The Wizard” is interfaced to the laboratory’s instruments, other customer #2 information systems and also to electronic data interchange (EDI) between their customers. Customer #2 performs laboratory research in several units e.g. patient research, quality control, cell production and stem cell registry which means that most of the employees use “the Wizard” daily. Customer #2 doesn’t have direct LIS interfaces with the company’s instruments but the sample codes from the result files are saved on “the Wizard”. Also the company’s instruments allow semiautomated work queues and the sending of laboratory results to “the Wizard”. Improvement would be to fully integrate the company’s instruments and get the full benefits of the bi-directional LIS interface. This would reduce some manual labour and streamline the laboratory’s workflow. For customer #3 LIS confirms research requests on instruments and sends the results to LIS. Due to the compact answer it's hard to say if customer #3 uses LIS for wider range of features. If not it would be practical to take the full advantage of LIS’ different applications.

This paragraph reveals the good qualities associated with LIS. The best feature of LIS according to customer #1 is that the laboratory only need to use one system besides instrument GUIs which depending on the instrument require more or less from the users. Other great qualities to LIS listed by customer #1 are its user-friendliness, that it applies fairly well to the process and automated flagging of laboratory results. Customer #2 also mentions the user-friendliness of “the Wizard” through activity-specific configurations and customisation. Additionally “the Wizard” has all the functionalities for everybody for smooth working experience in the laboratory. Customer #3 lists automated transfer of research requests and results as the best features of LIS. User-friendliness and automation of processes seem to be the common nominator according to the customers when it comes to good LIS features.

Contrary to the last paragraph on this paragraph we deal with the issues occurred on the customer LIS. Customer #1 rarely has the issue of their LIS slowing down and upgrading the system is cumbersome. Upgrades may cause issues when the systems operating logic changes between system versions. Additionally rerunning of sample sets and sample queueing may be difficult as the tasks demand some knowledge from the users. Also the lack of being able to manually remove samples from work queues is seen as an issue. For customer #2 as the main users of “the Wizard” are laboratory professionals problem situations are dealt swiftly and flexibly. However as there are so many activity-specific customisations on the system using “the Wizard” for features not included in the normal laboratory routine can be troublesome. Customer #3 finds it troublesome when there is overlap in sample coding. In other words the instrument finds a previously used research code which may already include a research request. This can confuse the system and some manual work to fix the issue may have to be done. Most of the issues mentioned by the customers seems to deal with abnormalities in the normal workflow or be caused by system upgrades or such. The normal LIS workflow at the customer sites seems to work as intended most of the time.

Customer representative #3A very well says that:

> “When it (the LIS) is working it helps/speeds up research requests/response traffic and relieves laboratory assistants who were formerly logging patient data mostly manually.”

The data handled by the customer laboratories vary by the function of the laboratory. Customer #1 listed a wide variety of data processed daily. These are sample IDs, sample sets, personnel data, instruments data, reagents, processing time, measurements (process controls), analysed results and sample approvals, sample plate comparison (with barcode), instrument sample IDs and instrument run protocols. Customer #2 lists laboratory results from patients, blood donors and quality control as the daily processed data. Customer #3 handles research requests and test results of samples. We can see that the scope of different data processed by the laboratories is large. The limit and scope of data processed is for the laboratory to decide.

Customer representative #1B thinks that:

> “My personal opinion is that LIS has to be highly configurable even so that the LIS includes the possibility to write your own scripts for example to automate processes.”

When asked for features that would be welcome but are currently lacking in their LIS the answers varied between the customers. Customer #1 would like to be able to comment on the results in the system after sample runs and correct instruments or reagent lots that were incorrectly chosen. So some additional manual type activities would be preferred by the customer if needed. Customer #1 would also like to have automatic reports, for example, from active reagent lots, run processes and interrupted or cancelled processes. So further automation would be welcome as well. Lastly customer #1 would like to have better readiness for interfacing laboratory instruments to the system but this also demands more from the instrument SW. Interfacing LIS and instruments of different manufacturers has its own challenges and takes some extra effort from LIS specialists, HW specialists and the LIS vendor. Making the LIS itself more compatible to wider range of laboratory instruments would make the system more user-friendly. Customer #2 ponders that there’s probably wishful thinking on improving many features but especially expanding EDI connections with their customers would be desirable and having more easy-to-use options for statistics and search. So even though there seems to be a general satisfaction with the system among customer #2 there is always room for further improvement especially in connections between systems. Customer #3 wishes for the ability to attach laboratory results to the other results describing the patients clinical status. This could help in diagnosing disease and improve patient care and treatment.

Customer representative #1A sums up LIS’ status perfectly:

> “Definite tool for a modern laboratory.”

The questions were rather superficial and didn’t go too deep into the subject which could have affected the depth of some of the answers. Also the persons relation to LIS and everyday urgency of laboratory work might have affected

some of the answers. Despite the narrow scope of the survey it still produced interesting answers to work on with.

6.2 Analysis of Interview

This analysis follows the interview structure systematically and aims to portray the interviewees answers and viewpoints as accurately as possible. The author discusses what was spoken during the interview and makes comments and ponders possible solutions if any. The interviewee is an application specialist with a ten years' experience of working in clinical environment. Their work has included interfacing of information system automation and several LIS integration projects with variety of different laboratory instruments. The interviewee hasn't been involved in any actual customised integration projects of instruments that wouldn't speak some standard LIS language like HL7. This could be a sign of how standardised anything involved with LIS is nowadays.

As a medical laboratory scientist specialised in molecular biology the educational background of the interviewee isn't directly related to LIS. However the clinical education formerly involved some work with LIS. The system had manual input of results as automated systems weren't integrated back then. The interviewee has worked in clinical laboratories and biotechnology companies and through their special interest in instruments and IT moved towards to more LIS related work. As an application specialist the interviewee has worked both in life science and in clinical diagnostics. The interviewee explained that in the clinical side it is of utmost importance that data transfer is smooth without interruptions and/or typing errors which could affect patient results. In Finland there is a need for a Finnish speaking application specialist as an interpreter between the customers and vendors. The application specialist understands both of the parties and is able to explain to the customer the needs of the LIS integration team and vice versa. This reveals the interdisciplinary nature of LIS integration projects as besides professionals of specific fields there is need for specialists whose expertise overlaps different scientific fields.

This is important for a smooth system integration and contributes to a successful project.

During their time as a medical laboratory scientist the LIS involved was a sample management system in a screening laboratory. The system performed pharmaceutical drug screening e.g. cell culture on microwell plates and drug molecule collections. These can hold hundreds of thousands of drug molecules that are being research for their effect on human cells. From this data the relevant drug components for any given research are picked from. This is a similar LIS solution that is typical for biobanks. Biobanks collect biological samples and the health data associated with the sample. This grants access to resources that are invaluable for high level medical science research. This particular LIS is a very sophisticated system related to compound management. The reason is that there are so many samples, tens of thousands, to research and to pick up by the system. For this reason the system recognises and monitors the pharmaceutical samples from the barcodes attached. The system lists which drug components are desired, knows where to find it and sends the information to a storage system which picks up the desired sample and moves it to the automated system and transfers the information to maintain traceability of the compound. This kind of system has to be very well designed and highly reliable for there are so many variables when handling so many samples. It is hard to imagine what are the procedures, methods and the amount of work that it takes to run this kind of processes without laboratory automation. The author would be very intrigued to see this kind of system in person to have a better understanding of it as it is a very interesting platform indeed. [25]

On the clinical side the interviewee has worked with uni-directional and bi-directional LIS from different vendors. From these times the LIS have developed fundamentally when it comes to user interfaces. From what they have seen in laboratories the interfaces of patient data management systems are still very archaic. The interfaces of patient data management systems reminisces of the times of disk operating systems contrary to modern LIS SW which are very much present-time. It might feel a bit strange that some of the systems are

outdated by modern SW standards. As the patient data systems are separate from the integration between the LIS and instruments it could be more challenging to make larger upgrades on the patient systems. Opposed to clinical laboratories life science laboratories often rely on more sophisticated and modern systems overall. On some time span upgrading or modernising the patient systems may be reasonable due to patient data security, usability etc. But as long as the systems work as intended it is justifiable to keep them operating.

The interviewee tells that LIS can be found from most modern laboratories despite the integration having a price tag as a bi-directional LIS minimises manual errors and at a minimum automates data transfer. They say that manual errors are the most common mistake in the workflow however it depends on the amount of samples handled whether the integration is profitable. As sample amounts increase laboratories prefer to integrate to LIS. The one-time charge consist of the integration from the LIS vendor and the integration package which can be supported by a bioinformatics specialist. Attitude towards LIS in central laboratories is more positive as the knowledge of the system is broader whereas in smaller health centres the users are usually nurses. The amount of samples handled in health centres are still relatively high so the LIS has to operate immaculately in order to handle samples effortlessly, fast and smooth. The LIS connection cannot be a burden for the users as it has to lessen manual labour. What is wanted of the system really depends on the type of research performed. Some laboratories only need to know if their results are positive or negative but others may need functions like alarms during anomalies, attachment of pdf reports and different sort of medical opinions. LIS should be flexible enough to allow customisations to satisfy the customer and vendor. It is possible to integrate almost any instrument to LIS even when essentially not being LIS compatible. If an instrument is connectable to the internet there are ways to build integration packages. This is managed by building interfaces through web folders to which the instrument saves data and from which the LIS retrieves the data. It can be said that acquiring of LIS should be evaluated case-by-case but in any laboratory exceeding certain amount of sample runs it is a

profitable system to have. LIS are also very adaptable and almost any kind of instrument set up is capable of integration.

The data handled by LIS especially on directly integrable systems is bioinformatic text files including LIS specific code language. In customised cases the files may be .xml, .csv or Excel files so the data can be in many different forms as long as the format has been defined for the system. Interpreting the data depends on the data format but in most cases it takes a professional like an application specialist versed in the system to understand the data. The laboratory technicians working with the systems may have some elementary knowledge of the data. As LIS vendors are focused in coding they generally do not know anything about the research being conducted. For this reason customised solutions always demand meetings with the LIS vendor, customer, instrument provider and possibly a LIS integration team. Customisation always demands substantially more work during the integration but the instruments that speak LIS languages like HL7 make the process easier. Laboratories ought to have a LIS contact person trained by the LIS vendor for co-operation. Here the interdisciplinary nature of LIS integration projects surfaces again. Expertise is needed from bioinformatic coders to laboratory scientists and anything between.

When asked for the benefits of LIS the interviewee listed the following:

- Streamlining of laboratory workflow which reduces manual labour
- Reducing errors
- Bi-directional LIS connection makes the workflow very easy
- Transfer of preliminary results
- Frees laboratory workers for other tasks

These statements are generally similar and in line with chapter 3.2 of this thesis. When asked for issues related to LIS they couldn’t think of anything directly caused by the LIS itself as typically the systems perform well. Most of the time the integration builds have gone as planned. Typical challenges relate to changes in run protocols. It is important to assure that changing the protocols

doesn’t affect the LIS code itself. Even small change in the code can end in empty results. Thus the application specialists need to be aware of any changes or upgrades on the system. The interviewee wanted to point out one example when an issue occurred. This happened when an instrument was integrated to a new LIS and an error code was given on the instrument GUI. The integration was successful in the end but it required the combined effort of the LIS and application specialists of the instrument manufacturer, the customer, the LIS vendor and the network operator. The amount of different variables affecting LIS during upgrades or changes to the system creates its own challenges. Other issues the interviewee wanted to point out were:

- Data transfer issues especially during or after network upgrades
- Issues occur after computers are upgraded or replaced
- Issues may occur during the early stages of LIS integration due to compatibility

This seems to suggest that most of the time the issues point to networking rather than the LIS itself. Nevertheless like during any system project there is always some configuring involved in LIS projects alike.

The interviewee thinks that LIS are well suited for the current needs of laboratories. In diagnostics artificial intelligence (AI) is still in its translational phase and as such research on how LIS could benefit from AI is in its initial stages. The data created by AI based on scientific findings isn’t fully reliable as the data is very multidimensional. AI could be very helpful in screening genome sequencing data as this includes a huge amount of information. The possibilities of AI in diagnostics remains to be unveiled and there is high potential in LIS utilising AI. The interview was concluded here with the envisions of potentially applying AI to LIS. Overall a very educational and a good meeting.

7 Discussion and Conclusions

This chapter processes the results gathered, ponders what was learned during the composing of this thesis and mulls the possible improvements for LIS projects. This part aims to answer research question 3. The chapter also concludes the thesis.

7.1 Conclusions

The idea of mixing different methods of literature review, survey and interview proved to be a rewarding scheme. Doing literature research and review worked as a backbone in understanding LIS and related technologies. It felt mandatory to have this knowledge before conducting the survey and interview. The survey gave a good cross cut across different laboratory layouts and workflows. It created an idea how similar and varied work in different laboratories can be. The interview managed to dive into the subject of LIS in great detail. The stories told by the interviewee regarding their own LIS experiences were highly interesting and provided an even further comprehension of the subject.

Many authors, case studies, the survey participants and the interviewee seems to recognise LIS' position as a valuable tool in laboratory work. They agree on several beneficial aspects of the system. These are reduced manual labour and streamlining of laboratory workflow, cost savings, improved efficiency, increased productivity and decreased errors. LIS related issues more often seem to be caused by something other than the LIS itself. Different issues are errors during SW, HW or network upgrades, system slowness and compatibility issues during early stages of LIS integration. The LIS architecture can be very sophisticated, the systems monitor and control daily lab work and process large amount of laboratory data. Despite this there are some features that the systems are lacking like better readiness for interfacing instruments and other database management systems, further automation of reporting and some manual features like commenting on results. Generally the current LIS adapt

splendidly to modern laboratory needs and it is a definite tool in modern high input laboratories.

Finding information on what is truly unique for LIS implementation and integration projects and specific for LIS project organisations proved to be a somewhat challenging task. There were no studies found on this. However the one aspect that circulated over the literature research, the survey and the interview was the interdisciplinarity of the LIS projects. LIS projects have very interdisciplinary nature due to having professionals from many different fields of science. On the laboratory side there are the laboratory technicians and scientists that have background in microbiology, medical laboratory science etc. On the LIS vendor side you have bioinformatic scientists and software engineers. Between these extremities there are LIS application specialists, health informatics engineers, network engineers, project managers etc. The range of specialists involved depend on the project and the expertise wanted and needed for the project. Perhaps somewhere here lies the benefits that a field based LIS integration specialist could bring to the company. Certainly there are no downsides to anyone involved in LIS projects in having a wider understanding of the systems. Having knowledge of LIS would at least make the co-working easier among the different fields of science taking part in the project. As there is no concrete work done to study and prove this it is hard to evaluate the effects that this kind of specialist would create though. Possibly this could be a good starting point for another thesis.

7.2 Final Words

The authors experience of LIS prior to writing this thesis were mostly limited to times when installing clinical laboratory instruments with LIS. This included co-work with the local hospital IT team and the LIS provider to make sure that the information from the device was being sent to the LIS. The full meaning of the abbreviation LIS was not in the vocabulary of the author before starting to work on this thesis either. Instruments were either integrated to LIS or they weren’t. As long as the instrument was working there really wasn’t a need for a deeper

insight of what LIS or LIMS are. What was important for the installation was that the instrument stated that a connection to LIS or LIMS was successful.

When the discussions about the thesis started at the company the author got some links to study the subject from the company LIS integration team manager. At this point the thesis background research was still at the starting point. It was in hopes that the thesis could be done on an actual customer LIS project and the project could start during the first half of 2023. The idea was to study the effects of a fully integrated LIS on an existing laboratory instrumentation at the customer site. Once this project was cancelled the thesis process got on hold. This also resulted in some motivational issues as there needed to be some sort of work around to exploit the already researched material for the thesis. The declined motivation caused some scheduling issues and a feeling that the thesis was in a dead end.

After some more or less uninspired months during the middle part of 2023 and general frustration towards the thesis the literature background research got started in the fall of 2023. This process lasted to the spring of 2024. At this point the writing had a couple of shorter hiatuses and the thesis writing became less amusing. This was until the practical methods in the form of the survey started. The survey started in the spring of 2024 and lasted to the summer of 2024. The interview continued the practical methods during the summer of 2024. Transcribing the survey and interview took place in the end of the summer 2024. The fall of 2024 was the turning point in the writing as the reality of having to graduate in 2024 hit the author. Additions to the literature background were done and a literature review based on the literature research was done. Following this were the lists of recommendations for LIS projects based on the background research of LIS implementation and integration. Finally the survey and interview were analysed. This end part of the thesis writing was the most productive and interesting part of the whole study process. These were the parts during the study when writing was pleasant and even fun. Sensations of happiness, fondness and proudness towards one’s own work were realised. Substantial personal and professional growth was gained during the study.

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Appendix

Kyselylomake: LIS

1. Onko laboratoriossanne käytössä LIS? Jos on niin minkälainen systeemi on kyseessä? Jos ei ole niin miksi ei ole?

2. Miten LIS palvelee laboratorionne päivittäistä työtä? Jos teillä ei ole LIS käytössä, niin miten LIS voisi hyödyttää laboratoriotanne?

3. Mitkä ovat parhaita LIS:n liittyviä ominaisuuksia?

4. Mitkä ovat yleisimpiä LIS:n liittyviä ongelmia? Tai mitkä voisivat olla ongelmatilanteita jos LIS ei ole vielä laboratoriossanne käytössä?

5. Minkälaista dataa LIS laboratoriossanne pääasiallisesti käsittelee/käsittelisi?

6. Minkälaisia lisätoimintoja LIS mielestänne kaipaisi jo nykyisten lisäksi?

7. Mitä muuta huomionarvoista liittyen LIS yhteyteen haluaisit mainita?

Haastattelupohja: LIS

1. Esittelisitkö itsesi ja taustasi?
2. Miten koulutustaustasi liittyy LIS:n?
3. Miten työsi liittyy LIS:n?
4. Minkälaisia LIS ratkaisuja/systeemejä on olemassa?
5. Minkälaisia kokemuksia teillä on LIS:n liittyen?
6. Miten LIS:n suhtaudutaan nykyään?
7. Mitä systeemiltä voidaan odottaa?
8. Miten LIS palvelee laboratorioiden päivittäistä työtä?
9. Minkälaista dataa LIS laboratorioissa pääasiallisesti käsittelee?
10. Mitkä ovat erityisen hyödyllisiä LIS:n liittyviä ominaisuuksia?
11. Mitkä ovat yleisimpiä LIS:n liittyviä ongelmia?
12. Mitkä voisivat olla ongelmatilanteita?
13. Miten LIS on muuttanut laboratoriotyöskentelyä?
14. Miten LIS on muuttanut omaa työskentelyäsi?
15. Minkälaisia lisätoimintoja LIS mielestänne kaipaisi jo nykyisten lisäksi?
16. Jos nämä toiminnot olisivat jo saatavilla miten ne hyödyttäisivät LIS:n kanssa työskenteleviä?
17. Mitä muuta huomionarvoista liittyen LIS yhteyteen haluaisit mainita?