



CHOOSING & USING A LIMS

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Introduction

The main drivers for the implementation of a Laboratory Information Management System (LIMS) are two-fold. From the business perspective, increased efficiency, an increase in throughput, faster time to market for drug manufacture and increased speed of decision making make a LIMS system a valuable business tool. Companies, especially pharmaceuticals are expected to operate within a tighter regulatory framework. A LIMS system can help an organisation achieve this through the use of appropriately approved systems.

Types of System

There exist various flavours of LIMS systems that are typically used within the different stages of the drug development lifecycle. Many LIMS providers are now suggesting that customisation should not be performed on a LIMS system as the cost of the customisation may be relatively small compared to the cost of re-validation for GAMP compliance for example. In this respect, it is often desirable to choose a LIMS for a specific purpose analogous to using a specific Microsoft Office application for a particular need. Therefore, an organisation may have many LIMS for the various stages of the drug lifecycle for example.

Drug Discovery

For drug discovery purposes, many LIMS systems have the ability to design a workflow to suit the laboratory. Samples can then follow particular workflows, be linked to further processes within the laboratory and contain functionality for plate handling and the associated pooling and replication of samples and sample aliquoting. Typical systems are designed for medium to high-throughput laboratories and include functionality to design experiments, control consumables, reagents and assays as well as subsequent analysis.

Manufacturing/Quality Assurance

For manufacturing and QA purposes, LIMS are designed to ensure high productivity and quality for analytical testing laboratories. Typical systems allow for entering, tracking, receipt of samples and automate the workflow of result entry, approval and reporting through to generating certificate of analyses for example. In order to meet the demands of the modern laboratory, modern LIMS systems are not one of many stand-alone islands of automation but are expected to integrate with Chromatography Data Systems (CDS) and Enterprise Resource Planning (ERP) systems such as SAP.

Functions of a LIMS System

A typical LIMS has many functions. Some of the operations and abilities of LIMS are listed below.

- ❑ Paperless office. Acquisition and manipulation of electronic data is faster than paper based processes.
- ❑ Automation of regulatory compliance. Compliance to FDA 21 CFR Part 11 can be achieved via implementation of an appropriately approved system. A LIMS system will identify users as they access the system and will log specific actions that the user performs on entities within the system. All of this allows for proper auditing to be performed ensuring that it is known when, by whom and why an entity was changed for example.
- ❑ Sample Tracking. This includes the logging of samples in the LIMS, sample receipt (registering the physical presence of a sample), sample test result entry and approval. A LIMS can then automatically generate a certificate of analysis for example.
- ❑ Integration with Patient Information Systems (PIS). A LIMS system can be used to manage samples from patients within a hospital or forensic environment for example. A hospital will use a PIS to manage patient core data that will then integrate with a LIMS in order to manage sample related data. Such interfaces are realised through the adoption of open-standards such as HL7 (see <http://www.hl7.org.uk>).
- ❑ Integration with ERP systems. In order to manage resources within an organisation in an automatic fashion, a LIMS will often need to integrate with ERP software such as SAP R/3. Such a system can alert a purchasing department if a raw material fails inspection or goods can be readily shipped if a manufactured lot passes QA checks. Many of the commercial LIMS providers work directly with SAP for instance so that an out-of-the-box LIMS is certified compliant with the SAP Quality Management Inspection Data Interface (QM-IDI).
- ❑ Integration with instrumentation. Many types of instruments and/or robots can be involved in the drug discovery/manufacture lifecycle. These instruments may be used for gene sequencing, high-throughput screening or proteomics for example. Data used by and generated by such instruments/robots will need to be maintained by a LIMS. In order to ensure compatibility

with many systems, a LIMS will adopt standards based mechanisms such as OLE for Process Control (OPC) to provide such functions. Other standards are now emerging for the integration of software systems with laboratory instruments to streamline such processes and ensure future-proof systems. AnIML (see <http://animl.sourceforge.net>) is one such XML based standard for the interchange of data between analytical instruments.

- ❑ **Business Intelligence Functions.** At a higher level than the laboratory, organisations will need to realise the costs of reagents, consumables, staff costs etc. A LIMS will often be required to generate this information at an appropriate level.
- ❑ **Design of Analytical Methods.** A laboratory will have sets of analytical tests that it will perform that should be readily associated with samples. A LIMS allows for the design of complex and varied analytical methods that also allows for quality specifications to be assigned. Specifications may be associated with a method for the purposes of quality, compliance etc.
- ❑ **Archiving.** A LIMS system used for manufacturing or drug discovery purposes will generate vast quantities of data. A LIMS system would be expected to archive data in order to leave the operational system running at peak performance.
- ❑ **Customisation.** A global organisation may require that localisation of the system is required in order to present the system in the correct language, date formats etc. Additionally, a LIMS is a very complex system and only a small subset of the system may be required. Therefore a LIMS system may allow for the customisation of screens in order to present a more simplified interface of commonly used functions. Many LIMS providers now offer the ability to customise their LIMS via an API. This can be more beneficial than “programming” customisations in that future upgrades of the software can be guaranteed to be compatible.
- ❑ **Extension of the LIMS.** LIMS have developed over many years now and LIMS vendors have built systems to suit the modern laboratory. However, an organisation may require that the system be tailored in order to meet specific business and/or regulatory requirements. An important aspect of a LIMS is the ability to extend and customise the system via an Application Programming Interface (API) without sacrificing the validity of the system.

- ❑ Security of the data. A LIMS will be expected to have security implemented over who can view/modify data and also maintain roles so that users are restricted in the actions that they can perform within the LIMS.
- ❑ Automatic scheduling of samples. Often it is required that samples should be automatically logged into a LIMS system at frequent intervals. An environmental site for example may require that samples are taken on a daily basis from designated sampling sites.
- ❑ Stability studies. Part of the drug manufacture lifecycle will involve the determination of the expiry date of a drug. These typically involve performing regular tests on many samples of a drug that are held in different storage conditions of temperature, humidity and packaging. Such studies will clearly last many years and involve thousands of samples of a drug.
- ❑ Quality Assurance. Quality assurance includes the testing of the raw materials of a drug, intermediate products through to the final manufactured product to ensure that the product meets its specification at each stage. A lot or batch is the common term within a LIMS used to describe a collection of samples associated with one or more steps of drug manufacture.
- ❑ RFID tags. An emerging technology within the LIMS arena is the use of RFID tags. Laboratory applications such as LIMS are based upon tracking unique items (such as samples). RFID readers placed in different locations within a laboratory enable the automatic tracking of samples from one room to another, a task that was previously performed using time-consuming barcode scanners. A LIMS that supports such an event-driven framework can then log the complete chain-of-custody for a sample and who is responsible for it. Forensic laboratories often require such stringent requirements on the chain-of-custody of a sample for example.

Choosing a LIMS

One of the first issues to consider when deciding to implement a LIMS is whether a commercial system should be bought or a bespoke system developed. Every laboratory is different and while a bespoke solution may meet your needs exactly, most modern commercial LIMS sell to a variety of labs and hence flexibility is built into their products.

Commercial LIMS represent many years of effort and experience in the field. A bespoke solution may require similar effort. Validation of a bespoke solution to satisfy regulatory requirements may take much longer than a commercial system.

As mentioned above, most LIMS incorporate an API in order that it can be tailored to meet the exact needs of a laboratory if the off-the-shelf solution does not meet them.

Various Internet resources exist that provide information on selecting a LIMS as well as information on implementing a LIMS, regulatory compliance etc. A few of these are:

- ❑ www.limsources.com
- ❑ www.lims.scimag.com
- ❑ www.limsfinder.com

Other issues to consider when purchasing a LIMS are:

- ❑ Compliance to regulatory requirements and the configuration of such parameters for an individual laboratory. A LIMS may need to fulfil its obligations for auditing and electronic signatures. However, this should be tailored to meet the demands of a laboratory since entering of electronic signatures will become burdensome if it is not required.
- ❑ The LIMS may have specific requirements for the infrastructure that is required in order for it to operate. This should be compatible with the organisations I.T. infrastructure. As an example, a client-server LIMS architecture may be deployed via a Citrix metaframe or Terminal Services but only if it is appropriate to do so.
- ❑ The cost of a LIMS system extends to beyond the licence fee. Costs of customising the system and the subsequent re-validation of the system to meet specific regulatory and business requirements can be very expensive.

Process of Choosing a LIMS

When choosing a LIMS, the following presents a structured process for the selection of a suitable solution.

- ❑ The existence of a valid business case for the new LIMS should exist as a pre-requisite. This should include the expected benefits of the new LIMS and the expected timescales for return on investment. The return on investment should be expected to be no less than 3-5 years for such a system and budget support should be available over this time.

- ❑ Generation of requirements of LIMS. A system-neutral requirements gathering exercise should document the expected requirements of a LIMS. The requirements should be understandable both by users and by I.T. staff. They should be measurable in order that it is possible to determine whether a requirement has been met or not. This is far ranging and should include:
 - ❑ High-level management requirements of the system for reporting.
 - ❑ Analyst requirements for the processes of sample receipt, entering of analytical results etc.
 - ❑ Quality/Laboratory Management requirements covering sample approval, generation of certificates of analysis, audit reports.
 - ❑ Laboratory protocols that are in place or are expected to be in place. These are presumably in place because they are deemed to be good. Therefore, a LIMS should build on these strengths.
 - ❑ Integration with other laboratory systems such as CDS, electronic laboratory notebooks, other instruments and robots.
 - ❑ Regulatory requirements covering the requirements to satisfy FDA regulations such as 21 CFR Part 11 (Electronic records and signatures) as well as GxP requirements.
 - ❑ Training that will be required for all levels of staff.
 - ❑ The existence of data pre-dating the LIMS may mean that a migration strategy is required for such data. Regulatory compliance may impose constraints that this data is kept in a readily available fashion. The importing of such legacy data can be highly complex and is likely to require a great deal of effort.

- ❑ An analysis of the available commercial products should be made initially focusing on the type of LIMS that is required, ie. for manufacturing or drug discovery purposes. For this purpose, LIMS vendors should be able to arrange demonstrations of their products as well as provide further information. The expected outcome of this stage is a short-list of the most suitable systems.

- ❑ Request for Proposals. Requests for proposals should be sent to the short-listed vendors. This is based on the requirements document produced and it is expected that vendors should indicate how each of your requirements is or can be met by their system. The RFP should also request information about the financial health of the company and its future plans. The LIMS would be expected to be functioning for many years. During its lifetime, upgrades and patches would normally be expected in addition to consulting on modifications for specific organisational needs. Another solution to this is to ensure that the LIMS source code is held in escrow to protect the organisation against possible loss of support by the vendor.

- ❑ Evaluation of proposals. The returned proposals should be evaluated using a scoring mechanism. A small number of the top respondents should be invited to provide detailed demonstrations of their systems. As most commercial LIMS are designed for typical processes in the laboratory, most respondents will readily meet 80% of the requirements. The winner should be the one that best allows the organisation to most easily achieve the remaining 20%.

Process of Implementing a LIMS

Following the selection of the most suitable system for your organisation, there remains several steps that should be followed to ensure the correct implementation of the LIMS. These steps are detailed below:

- ❑ Pilot the system. The system should be piloted within an identified laboratory within a business unit of the organisation before rolling out to further laboratories and other business units if it is to be.

- ❑ The system should undergo an Installation Qualification. This ensures that each step of the installation process is performed correctly and is accountable to an individual. The installation script will detail the step-by-step procedure for installing the system.
- ❑ The system once installed should undergo an Operational Qualification. An Operational Qualification ensures that each component of the system performs as intended within intended or representative ranges. A qualification script will detail the step-by-step procedure for qualifying the system and should include security, screen flow, data validation and data updates. A cross-reference between the operational qualification and the requirements should be maintained.
- ❑ Arrange on-going support and maintenance support with the vendor for “help-desk” support, bug fixing etc.
- ❑ Users will require training in the new system and importantly will want to see the benefits to them as individuals in their day-to-day job.
- ❑ Full-time staff will need to be dedicated to administering the LIMS and providing technical support.
- ❑ An “executive” for the system will need to be appointed who has overall authority and responsibility for the system.
- ❑ Follow-on activities will need to be identified. A commercial LIMS will have met the majority of your organisations requirements. Now, the process of implementing specific enhancements for your organisation will have to be planned.

Conclusions

Choosing a LIMS, whether you decide to build a bespoke system or purchase a commercial product is a large undertaking. A well-implemented LIMS can be an enormous benefit to an organisation but a poor implementation may drag on for years and erode the confidence of users within the organisation and customers. Once implemented, the LIMS needs continuing maintenance and assessment. Expert LIMS consultants can help you through this potential minefield.

Commercial Laboratory Information Management Systems

The following sub-sections provide details of various commercial LIMS that are available. This has been split into those that are designed for the high-throughput drug discovery markets and those that are designed for manufacturing/QA markets. A checklist at the end of each section provides a quick reference to the main features of the systems.

LIMS for Drug Discovery

Vendor **Cimarron Software**
Product Sierra Genotyping/Sequencing/Microarray/Proteomics
Web Site www.cimsoft.com

Cimarron produces four different products whose workflow mirrors that of a typical genotyping, sequencing, microarray and proteomics laboratory respectively. They specialise in producing Laboratory Workflow Systems (LWS) and their products are therefore highly tailored to specific domain work patterns.

Sierra Genotyping is a data management system for medium to high-throughput entire genotyping workflow. This can be integrated with a variety of genotyping instruments and software including those associated with STR and SNP genotyping and TaqMan allelic discrimination assays.

Sierra Sequencing is a data management system for storage and management of DNA sequencing data and chromatogram data files.

Sierra Proteomics manages the entire Two-Dimensional Electrophoresis-MALDI-ToF MS workflow, it is integrated with state-of-the-art instrumentation and is compatible with DeCyder™ software allowing the use of DIGE™ technology for the accurate comparison of protein samples.

Sierra Microarray is a data management system for the experimental design and submission of the biological sample to the capture of numerical expression data.

All four products are based upon a J2EE infrastructure.

Vendor **ThermoElectron**
Product Nautilus
Web Site www.thermo.com

ThermoElectron have two products aimed at the drug discovery market: Nautilus and Watson LIMS. The emphasis on their products is that they should be used out-of-the-box with no customisation.

Nautilus is designed for R&D laboratories and includes the ability to design workflows to meet the dynamic changing laboratory's needs.

The architecture is of a client-server architecture with a Windows front-end. Nautilus can be deployed using Terminal Services/Citrix in order to save multiple installations of the desktop client.

Vendor **ThermoElectron**
Product Watson LIMS
Web Site www.thermo.com

Watson LIMS was acquired when Thermo took over Innaphase Corporation. Watson is a highly specialised protocol-driven LIMS specifically designed to support Drug Metabolism and Pharmacokinetics (DMPK) and biological studies in drug development.

The system contains customisable security and audit configuration in order to meet specific 21 CFR Part 11 requirements. Because the system is specifically designed for DMPK studies, then very little configuration and maintenance of the system is required.

Vendor **Applied Biosystems**
Product LS*LIMS
Web Site www.appliedbiosystems.com

Applied Biosystems market Life Science LIMS (LS*LIMS) for the drug discovery market.

The system contains an easy to use drag-and-drop workflow editor in order to completely define laboratory processes. The system allows for the building of processes using pre-defined, reusable lists of activities, protocols and workflows. The system includes many out-of-the-box workflows to support

Applied Biosystems instruments including TaqMan SNP Genotyping assays, TaqMan Gene Expression Assays.

The system is built around an Oracle 9i database and utilises Oracle Reports for reporting purposes. A fully documented API and developer toolkit is available in order to extend and modify the system.

Vendor **LabVantage**
Product SAPPHIRE
Web Site www.labvantage.com

SAPPHIRE Life Science LIMS is the product from Labvantage for LIMS in the drug discovery markets.

SAPPHIRE can be deployed as a closed system compliant to FDA 21 CFR Part 11 or an “open system with appropriate controls”.

SAPPHIRE contains the ability to define specific workflows to meet the laboratories needs. It also automates complex multi-dimensional array management.

SAPPHIRE is able to integrate with industry standards for specific tasks in genomics, proteomics and HTS.

The level of instrument interfacing is advanced in SAPPHIRE. Rather than file passing mechanisms etc, SAPPHIRE is able to integrate with instruments and robots at the driver level enabling users to drive robots via methods developed within the LIMS.

LabVantage have also developed the proprietary Compass Implementation methodology. The purpose of this is to enable successful implementations of LIMS by taking customers through the process of plan, analyse, construct, transition, deploy and optimise. The intention of such a process is to minimize project risk and maximise project success.

SAPPHIRE provides integration with external systems such as instruments, robots, other analytical tools and ERP systems such as SAP.

SAPPHIRE is a web-enabled system. It is supplied with a configuration tool, Evergreen Studio Web Page Designer. This allows the system administrators to change SAPPHIRE web pages in order to meet system architecture, database configuration, user administration and business process automation requirements.

SAPPHIRE is based upon J2EE Application Server technology. As a result, the LIMS supports clustering of application servers and load balancing.

LIMS for Manufacturing/QA

Vendor	Labware
Product	Labware LIMS
Web Site	www.labware.com

Labware LIMS meets GLP requirements by providing full sample tracking, user certifications, instrument and calibration management, standards and reagents management, full auditing and compliance to 21 CFR Part 11, 50, 58, 210, 211 and 820.

As well as manual sample logging, Labware LIMS also contains automated sample logging via: Sample Scheduler, Calendar Scheduler, Environmental Scheduler, Process Scheduler allowing for samples to be logged according to frequency, interval, calendar and logic.

Labware LIMS can be integrated with ERP systems such as SAP R/3, BPCS, JD Edwards and Movex. Labware LIMS achieves integration with SAP R/3 via the implementation of the QM-IDI interface specification.

Labware LIMS also provides a seamless bi-directional interface to the Waters Corporation Empower CDS and Millenium32 software.

Labware LIMS is able to interface to a variety of instruments using Labware's LabStation module. LabStation provides the following mechanisms for instrument integration: RS-232, file based and reports stored in NuGenesis Unify / Vision (Version 5.2 or higher) format. Once the result has been acquired, LabStation then applies a parsing algorithm to the result in order to store the data within the LIMS. LabStation comes with a complete set of pre-built parsing scripts for many popular brands of instruments. NuGenesis is a Scientific Data Management System (SDMS) produced by Waters Corporation.

For QC purposes, Labware LIMS includes the Lot Manager to integrate the physical view of manufactured materials with the sample centric view enabling checking of a manufactured lot or batch against the specification. Specifically, the Lot Manager has been interfaced with the SAP R/3 Quality Manager (QM) module. The SAP QM module drives the creation of lots within the LIMS. Once testing is complete, a usage decision is then passed back to SAP QM. Labware LIMS also provides functionality for stability studies.

Within GAMP, Labware LIMS qualifies as a category 4 system as it is a configurable system where customisation is not necessary.

Labware LIMS is a Microsoft based client-server architecture. The server is able to run within Windows and UNIX environments and can interface to many ODBC compliant databases including: Oracle, SQL Server and DB2. In order to move to thin client architecture, the client application is compatible with Citrix.

Vendor **Labvantage**
Product SAPPHIRE
Web Site www.labvantage.com

SAPPHIRE can be deployed as a closed system compliant to FDA 21 CFR Part 11 or an “open system with appropriate controls”.

SAPPHIRE is able to conduct QA/QC testing to ensure that finished products meet particular specifications.

Stability (or shelf-life) studies can be performed utilising SAPPHIRE. SAPPHIRE includes the ability to track a variety of conditions within a particular protocol including freeze/thaw.

Vendor **StarLIMS Corporation**
Product StarLIMS
Web Site www.starlims.com

StarLIMS is a highly configurable and customisable systems built around an n-tier architecture. The system allows users to use their own database tables for the purpose of extending the system. It utilises web services and also has a SOAP client.

The system provides the functionality for sample scheduling, automatic test processing, chain-of-custody utilising RFID technology and QA/QC.

StarLIMS have a premier agreement with Waters Corporation and therefore offer CDS integration with their Empower/Millennium32 software.

StarLIMS also has an integrated RFID module. This allows the LIMS to manage the information received from multiple RFID readers set up within a site. The LIMS then logs the chain-of-custody of sample and allows for the complete viewing of events connected to that sample.

StarLIMS is able to interface to SAP QM and has SAP certification for this. The LIMS is able to integrate with many process automation software systems including AspenTech, Foxboro, Honeywell, OSI and ABB systems.

StarLIMS utilises Business Objects Crystal Reports for reporting purposes.

Vendor	PerkinElmer
Product	Labworks ES LIMS
Web Site	www.perkinelmer.com

Labworks LIMS has comprehensive support for multiple languages including native versions in French, German, Italian, Chinese, Japanese and Spanish.

This QA/QC system has interfaces to ERP systems such as SAP R/3, JD Edwards and AspenTech. Additionally, Labworks interfaces to Northwest Analytical Quality Analyst (www.northwestanalytical.com) in order to generate Statistical Quality Control (SQC) charts and calculations. An interface to ArcView Graphical Information System (GIS) from ESRI (www.esri.com) enables validation of sample collection data and the ability to reference it to other analytical and geo-referenced data.

Additionally, the system incorporates a Scheduler for automatic sample logging. A simple Windows style intuitive interface is also included, the LW Explorer. This allows a read-only hierarchical navigation of the data and imposes restrictions on what can be viewed according to the users role etc.

The server based architecture allows for users to connect via mobile telephone connections as well as LAN/WAN and Internet.

The system supports a variety of databases including Microsoft Access, SQL Server, SyBase, DB2 and Oracle. Reporting within the system is handled via Crtstal Reports.

Vendor **Autoscribe**
Product Matrix LIMS
Web Site www.autoscribe.co.uk

MatrixLIMS is a highly configurable product allowing for highly scalable systems used by 500 concurrent users or just a single user on a PC based system. MatrixLIMS includes a graphical workflow interface to represent the progress of a sample through the laboratory.

Autoscribe provide a low cost entry into the LIMS market place using a particular configuration of their LIMS called Matrix Express. This includes sample logging, work registration, worklist creation, result entry, validation and approval. This would be a typical configuration for a small analytical laboratory for example. This is a client-server application (where the whole system may be located on the same physical machine).

At the other end of the market, Autoscribe provide Matrix Enterprise designed for the use of multi-site global organisations. This configuration includes multi-language support. The system is Citrix compliant and also includes central management of upgrades to reduce the cost of maintenance.

Through the addition of various modules, Matrix LIMS can be configured for use in stability study management, nuclear, chemical, food and utilities domains. The system can be used with a variety of ODBC compliant databases including Oracle and SQL Sever.

The technology behind Matrix LIMS is purely Microsoft .Net. Using Windows Forms, Matrix LIMS utilises the same forms that are used on the web enabled version as with a client-server version.

Vendor **Quality Systems International (QSI)**
Product WinLIMS
Web Site <http://www.lims-software.com>

WinLIMS is described as a configurable product that doesn't require any customisations, except for additional reports that can have costly validation implications.

The system supports QA/QC batch processing, statistical graphing, formulation control and is FDA 21 CFR Part 11 compliant.

The system can be readily integrated with the following ERP systems: SAP, JD Edwards, Prism and Progress. Instrument interfacing is bi-directional.

WinLIMS offers a flexible solution depending on the size of the organisation and I.T. infrastructure available; WinLIMS can be used via a Windows thick client application (which is compatible with Citrix), Intranet/Internet and Pocket PC version where database connectivity is via a RF network connection.

WinLIMS supports a variety of databases including Microsoft SQL Server, Oracle, Sybase and SQLBase. Reporting is performed by Crystal Reports.

Vendor **Tribal Software**
Product Tribal LIMS/LDMS
Web Site www.tribalsoftware.com

Tribal Software market their product as a Laboratory Data Management System rather than a LIMS.

Tribal LIMS is a low cost solution based upon Microsoft Access but which allows interfacing to SQL Server and Oracle also.

Vendor **Applied Biosystems**
Product SQL*LIMS
Web Site www.sqllims.com

SQL*LIMS v5 provides functionality for automated sample logging and receipt, quality assurance and stability study requirements in addition to workflow processing in a manufacturing environment.

It is a configurable system with a fully documented API and through the adoption of open standards such as web services and XML provides for a highly extensible system. Through the use of Oracle Reports, further data mining functions can be readily added to the system.

The system also provides support for interfacing to SAP ERP systems and additionally a HL7 interface enables an interface to such compliant systems.

Through the Microsoft OS based IDM-LimsLink software, SQL*LIMS provides support for linking to any of the Labtronics range of instruments.

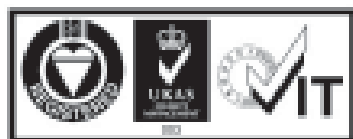
The server systems utilises an Oracle 9i database, Oracle Forms and Reports which are hosted by an Oracle 10g Application Server. The system therefore utilises a thin client web browser architecture that only requires the Oracle / JInitiator browser plug-in.

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