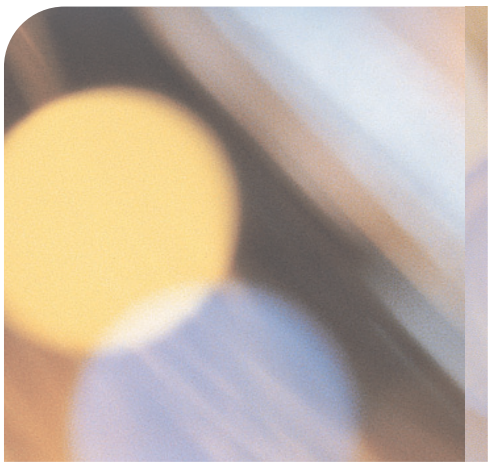

IT Solutions Focus

UK BIOBANK USES NAUTILUS LIMS™ ADVANCE LIMS TECHNOLOGY TO STORE AND ANALYZE BIOLOGICAL DATA

By Doug Holbrook and David Sanders

UK Biobank has chosen Nautilus LIMS™ from Thermo Fisher Scientific to track, store, manage and report on the biological data of 500,000 people as part of one of the largest medical research projects ever conducted. This implementation is expected to provide immediate benefits with regards to quality of generated results and subsequent scientific advancements.

"UK BIOBANK EXPECTS 15 MILLION ALIQUOTS RESULTING FROM THE FRACTIONATION OF THE BLOOD AND URINE. A VIABLE SOLUTION WAS REQUIRED, CAPABLE OF YIELDING REAL-TIME, DEPENDABLE ANALYSIS AND REPORTS AND PROVIDING SECURE ACCESS TO DATA AT ANY GIVEN TIME."

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BACKGROUND

Scientists have known for many years that the risks of developing different diseases are due to the complex interplay of different factors including lifestyle, environment, personal susceptibility, genes and luck. But despite this longstanding awareness, a clear picture of the combined effects of various factors on the risks of different diseases is yet to emerge. To date, there have only been incomplete or inadequate measures of potential risk factors which may yield over- or under-estimates of disease associations. There have also been cases when diseases have influenced risk factor levels.

UK Biobank is a major medical research initiative with the purpose of building the world's most detailed information resource in order to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses including cancer, heart diseases, diabetes, arthritis and various forms of dementia and to promote health throughout the society. UK Biobank is currently recruiting 500,000 people aged 40-69 from across the UK to take part in this long-term project expected to last for up to 30 years. This particular age group was chosen because it involves people at high risk of developing serious diseases over the next few decades.

Following consent, participants will be asked to give small samples of blood and urine for long-term storage and analysis and have some standard measurements such as blood pressure, height (standing and sitting), weight and bioimpedance, body fat / waist and hip circumference, hand grip strength, bone density and lung function. They will also be asked to complete a confidential health, lifestyle, memory, work and family history questionnaire while their routine medical and other health related records will be followed by UK Biobank over the next 30 years. UK Biobank will allow fully approved researchers to use these data to study the impact of lifestyle, environment and genes on the progression of illnesses. By analysing answers, measurements and samples collected from participants, researchers may be able to work out why some people develop particular diseases while others do not. This will help researchers to understand the causes of diseases better and to find new ways of preventing, diagnosing and treating many different conditions. Data and samples will only be used for ethically and scientifically approved research to provide prolonged and detailed follow-up of cause-specific morbidity and mortality.

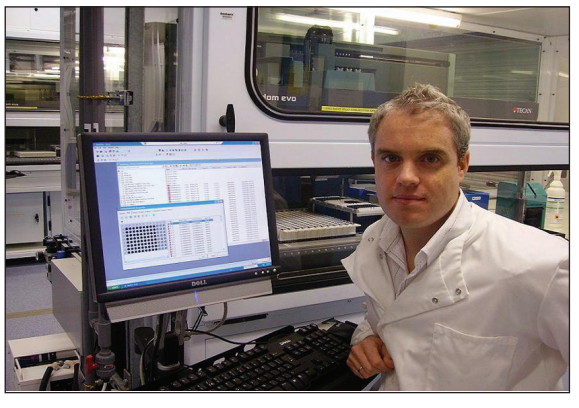

Figure 1. David Sanders, LIMS Manager, UK Biobank with Nautilus LIMS™ from Thermo Fisher Scientific

UK Biobank has the support of leading scientists from the UK and from around the world. The initiative is funded by the Wellcome Trust, the UK's largest independent medical research charity, the Medical Research Council, the Department of Health, the Scottish Executive and the Northwest Regional Development Agency. Furthermore, UK Biobank has the backing of many of the UK's major medical research charities, including the British Heart Foundation and Cancer Research UK. The project is also supported by the National Health Service while working closely with Generation Scotland, a complementary study underway in Scotland.

THE NEED FOR LIMS

UK Biobank will follow a certain procedure during the lifetime of the project. At the end of each day, participant data and samples will be transferred securely to the UK Biobank coordinating centre. Following sample processing in the central laboratory, multiple aliquots (28 per person) will be stored in an automated -80°C working archive and in a back-up liquid nitrogen store at a geographically distinct location for security. Each participant will be issued with a Universal Serial Bus (USB) memory key which will act both as an identifier and as a back-up temporary data storage device.

Bar-coded vacutainer tubes will be used to collect blood and urine samples using pre-prepared racks. Immediately following collection, all vacutainers containing blood and urine will be transferred to the sample processing area. Following the collection of samples, staff members will verify from the computer that the participant has completed all of the tests. Processing of blood and urine samples at the assessment centres will be minimal.

After collection of a complete set of vacutainers, the unique bar-code on each one will be scanned into the assessment centre IT system that links each vacutainer with the unique participant identifier number. This is important to link the participant data from the assessment centre with the start of the laboratory data structure in the central Laboratory Information Management System (LIMS).

When the vacutainers arrive at the central laboratory, they will be scanned and compared against the LIMS data file from the assessment centres to ensure that the correct tubes have arrived and the laboratory data file can be linked to the other participant data. The vacutainers will then be processed using automated systems with times and temperatures of all operations and operator identifiers logged in the LIMS. If any samples will be required for subsequent research, their bar-codes will be identified by the LIMS to produce an order which will be transferred to the archive inventory to retrieve the racks containing the required tubes.

In an attempt to address the needs of this challenging and complex procedure, UK Biobank decided to employ Thermo Scientific Nautilus LIMS to store and track the tremendous amount of data from the analysis of samples from the 500,000 volunteers. UK Biobank expects 15 million aliquots resulting from the fractionation of the blood and urine. A viable solution was required, capable of yielding real-time, dependable analysis and reports and providing secure access to data at any given time.

WHY NAUTILUS LIMS?

"The flexibility, adaptability and stability of Nautilus LIMS combined with Thermo Fisher's long-established experience serving the health sciences and pharmaceutical industries made Nautilus LIMS the obvious choice for the data management of this massive project," said David Sanders, LIMS manager for UK Biobank.

"UK Biobank is expected to grow from one clinic to 6 by the end of 2007, with all sites feeding biological samples that will be entered into and tracked by the LIMS. Several decision-makers on the LIMS selection team had previous experience with Nautilus LIMS and feel confident that it is the most appropriate tool for this project."

Nautilus LIMS is designed for the unique requirements of R&D laboratories. It includes patented workflows technology with a flexible and intuitive interface to graphically map laboratory workflows of the sample life cycle. Full functionality for plate handling and manipulation can be used to track plate movement and genealogy, while standard integration functionality allows data to be easily imported without coding from a variety of analytical instruments.

With its built-in instrument integration, the system offers productivity gains right from the outset whereas the flexibility of the software offers the option to build extensions in order to interface to other systems. The system is compatible with Microsoft® Office while being designed, developed and supported within an ISO 9001/TickIT environment.

Apart from the analytical and integration capabilities of Nautilus LIMS, there were also other factors that influenced the decision of UK Biobank to implement this LIMS solution.

Thermo Fisher's service and support team is ideally located near UK Biobank's headquarters in Manchester meaning that they can follow-up on any possible implementation, maintenance and upgrade needs as soon as any issues occur. Furthermore, the solution is cost-effective being offered at an affordable price while incurring reasonable operational costs.

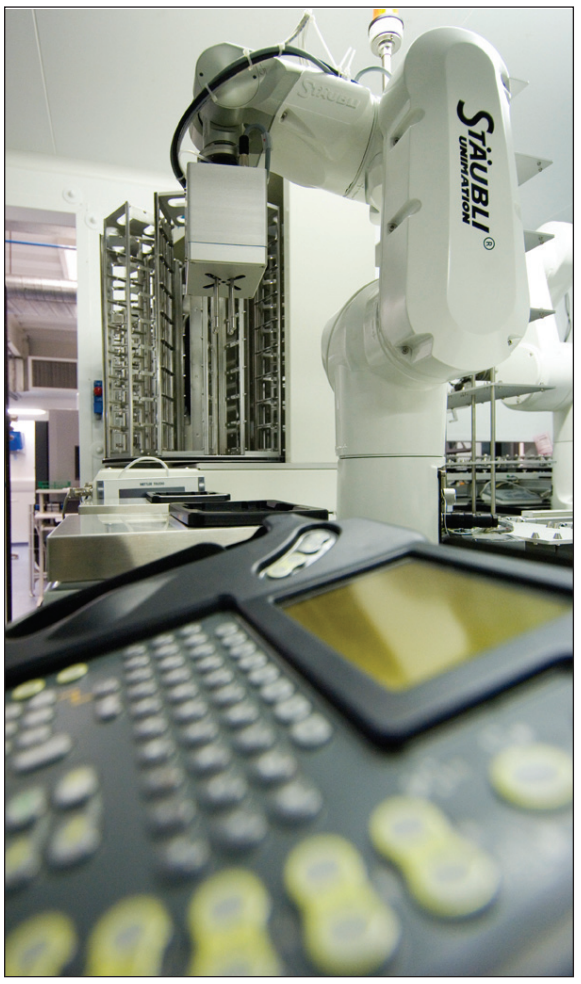

Figure 2. The fractionation robots in use at UK Biobank

Figure 3. The 1ml Thermo Scientific Abgene tubes

BENEFITS ACHIEVED WITH LIMS

The LIMS has been already tested for efficiency and accuracy in a three-month pilot study, which took place between March and June 2006, recruiting 4,000 participants from South Manchester. During the pilot study, the system was proven competent in storing location and linkage information between participants and samples/aliquots.

The system has managed to track the samples throughout the process and link them to the correct volunteer ID, to any plates that have been made from the samples and to the locations of samples and plates within the storage warehouse. It has also managed to maintain a record of the volume of samples used and the volume remaining. This has triggered replenishment from the back-up archive and has helped guide resource access decisions for depleted samples.

The integrated pilot study showed that automated interfacing and validation of data from robotic workstations worked well with no problems encountered. Nautilus' built-in process validation prevented human-related errors in data transcription. Samples from the integrated pilot were transferred to liquid nitrogen and hand-held data logging systems used to record the samples in the archive inventory. Subsequently, these hand-held devices were interfaced with the LIMS with 100% accuracy and all data records updated.

Though Nautilus offers flexibility in workflows required by R&D organizations, UK Biobank has configured the LIMS to follow certain and fixed workflows so that all samples follow the same protocols for testing and storage.

The flexibility of the solution will prove vital for the effectiveness of the project. In such a long-term study, parameters will change constantly requiring a constantly-changing LIMS. To appropriately archive the vast amount of data generated by the UK Biobank study, Nautilus LIMS will be part of an automated system that will receive samples, fraction them into appropriate vessels for testing, analysis and storage, and then track and store all data relative to the samples.

Data collection, resource management and data processing will be automated and results will be stored in a central database. The LIMS will be used to provide daily updates and management reports. Researchers will be able to track sample status and download final results in real time.

NEXT STEPS

One further area to explore is for the LIMS to include the ability to integrate very easily with the project's robotics in-house. Tools will need to be built in the LIMS to allow interface to extensive storage archives.

The aim of UK Biobank is to standardise on Nautilus LIMS across all of its sites allowing for biological analysis results to be automatically entered into and processed by the central repository. The LIMS will serve as a comprehensive inventory for the researchers who need to use the results. Moreover, the UK Biobank participates in a LIMS user group with two other biobank organizations using Nautilus LIMS, the Hunt Biobank in Norway and the Singapore Tissue Network. "The three organisations are doing similar work, using many of the same tools and intend to collaborate on methods involving Nautilus LIMS," explains David Sanders.

St. Louis, MO to Host LIMS Seminar

Accelerated Technology Laboratories Inc (ATL), and Microsoft have announced that on Friday, September 21st, 2007, St. Louis, MO will be hosting a free, educational seminar which focuses on why a Laboratory Information Management System (LIMS) is the key to streamlining laboratory operations and staying compliant.

The seminar is a morning event that will explore the current challenges that are faced in the modern laboratory and demonstrate how organisations are automating operations to increase productivity and data quality while reducing operational costs.

This seminar is ideal for Laboratory Operations or QA/QC Managers in the following industries: water/wastewater, environmental (air/water/soil), agriculture, chemical, food & beverage, life sciences and government (public health).

Attendees will learn:

- The considerations in the selection of a LIMS to streamline laboratory operations, improve data quality, eliminate mundane tasks and maintain regulatory compliance.

These include:

- Streamlining sample login utilising bar-coded labels.
- Automatically e-mailing updates based on user configured QC limits.
- Directly importing data from instruments, thus reducing transcription errors that result from manual re-entry of data.
- Automating reporting via fax, email or printing (final analysis reports, certificates of analysis, production, backlog reports, etc.)
- An understanding of the pros/cons of integration with enterprise systems (Financial/Accounting, ERP).
- How to increase communication across the organization with automated processes to achieve increased product quality, regulatory compliance and shorter turnaround times.
- How laboratory automation solutions can improve market effectiveness.

The seminar is hosted by Microsoft, a leading provider of laboratory database software (MS SQL Server) and Accelerated Technology Laboratories, Inc., a market leader in the LIMS space with their Sample Master® flagship solution.

ATL is a Microsoft Gold Certified Partner and has developed Sample Master to be tightly integrated with the Microsoft Office platform and the Microsoft Server System including MS SQL Server.