



CUSTOMER CASE STUDY:

Effectively Storing and Analyzing Biological Data at UK Biobank

UK Biobank is a major medical research initiative based in Manchester, UK. The company's goal is to build the world's most detailed information resource that can support a diverse range of research aimed at improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses and to promote health throughout society. UK Biobank chose Thermo Scientific Nautilus LIMS™ 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.

UK Biobank's Operations and Procedures

The relationship between a nation's health and poverty is well known, but the solutions for closing the gap between health provision for rich and poor are not so easy to find. A great deal of knowledge is available from different sources, but there is no comprehensive system for the systematic collection of data which can be used to establish the true impact of disease on a nation's prosperity, and vice versa. One aspect of this is being addressed by UK Biobank.

Over the next few years the UK Biobank is building a uniquely rich resource for inves-

tigating why some people develop particular diseases while others do not. During an initial recruitment period of three-and-a-half years, 35 assessment centres will be set up around the UK. The company is looking to recruit just over 500,000 participants by mid-2010. All information collected will be stored centrally and updated as each participant's health status is monitored.

The aim is to use as many participants as possible and collect as much detailed information from them as possible. The number of participants, responses to questions and quality of measurements are critical to a favourable outcome for this project. To

accommodate for the vast scope of this project, a comprehensive Laboratory Information Management System (LIMS) to collate, store, sort and retrieve the material in a useable format was required. In addition, the LIMS needed to be capable of yielding real-time, dependable analysis and reports and providing secure access to data at any given time.

In an attempt to address the needs of this challenging and complex project, UK Biobank selected Thermo Scientific Nautilus LIMS to store and track the tremendous amount of data generated from the analysis of samples. In addition to answering 200 life-style and medical questions using automated



touch screen technology, participants will donate blood and urine samples for a total of up to 15 million individual aliquots. All this must be tracked by Nautilus LIMS. For each aliquot the LIMS will store its parent, its grandparent, its rack barcode ID, its position on the rack, the location of the rack in the store and the aliquot contents, among other things. In total, UK Biobank is aiming to obtain several hundred million data points within the underlying database.

Format of the Study

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. Participants 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 this data to study the impact of lifestyle, environment and genes on the progression of illnesses. By analyzing 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.

Nautilus LIMS

First commercialized in 1998, Nautilus LIMS is designed to address applications that require more flexibility than a traditional enterprise LIMS. Flexible and robust, with automated plate handling and easily configured extensions, Nautilus is the LIMS of choice for many organizations.

Nautilus LIMS includes patented workflows technology with a flexible and intuitive interface to graphically map laboratory workflows of the sample life cycle. 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.

UK Biobank chose Nautilus LIMS as it is designed for the unique requirements of R&D laboratories. Without a clearly targeted and appropriate information management system in place, researchers would be unable to access and use the enormous information resource created by the project.

“The flexibility, adaptability and stability of Nautilus LIMS combined with Thermo Fisher Scientific’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 six, with all sites providing 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.”

Prior to joining UK Biobank, David Sanders had over seven years of experience in using Nautilus LIMS, and therefore championed its selection. Other factors in the decision include Thermo Fisher Scientific’s extensive experience and background as a LIMS supplier, and the flexibility of the software itself such as the ability to build ‘extensions’ in order to interface with other systems.

A strict procedure for obtaining and storing the information will be followed which allows the full potential of Nautilus LIMS to be realized.

Data Collection

Daily participant data and samples will be transferred securely to the UK Biobank coordinating centre. Following sample processing, 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.

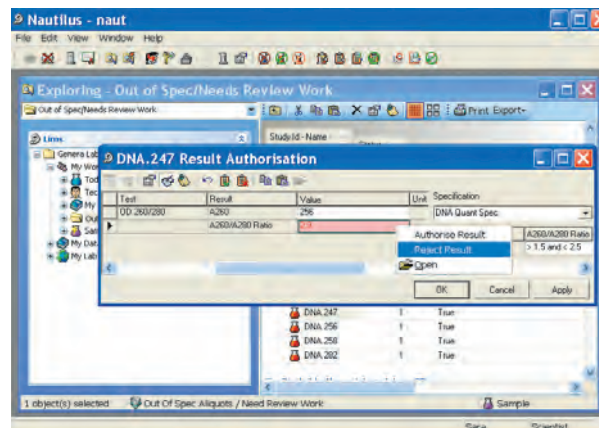
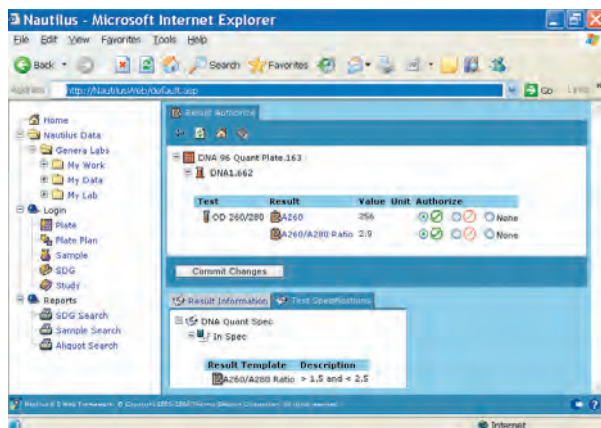
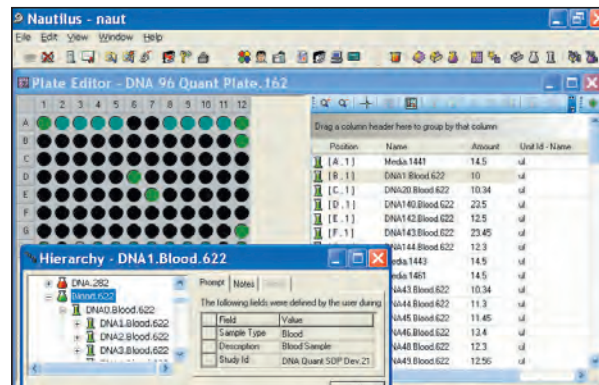
Bar-coded vacutainer tubes will be used to collect blood and urine samples using pre-prepared racks. Following the

collection of a complete set of samples, the computer will verify that the participant has completed all of the tests and the unique bar-code on each one will be scanned into the assessment centre IT system linking each vacutainer with the unique participant identifier number. This links the participant data from the assessment centre with the start of the laboratory data structure in the central Nautilus LIMS.

When the vacutainers arrive at the central laboratory, they will be scanned and compared against the LIMS data file from the assessment centres. 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 are required for subsequent research, their bar-codes will be identified by the LIMS to retrieve the racks containing the required tubes.

Benefits achieved with Nautilus LIMS

Nautilus was tested for efficiency and accuracy in a three-month pilot study, which took place between March and June 2006, recruiting 4,000 participants. During the pilot study, the system was proven in storing location and linkage information between participants and samples/aliquots.



After collecting the data, results can be reviewed and authorized on the web or within the Nautilus client.

It also maintained 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.



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 long-term study, since parameters will change constantly. To appropriately archive the vast amount of data generated by the UK Biobank study,

Nautilus LIMS will be part of an automated system that receives samples, fractions them into appropriate vessels for testing, analyses and then tracks and stores 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

The aim of UK Biobank is to standardize 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.

Conclusion

With the help of Thermo Fisher Scientific and its Nautilus LIMS solution, UK Biobank will enable scientists to gain unique insight into the genetic and environmental causal factors associated with a wide range of debilitating diseases, providing vital information needed to work on future preventative and curative measures.

For More Information

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In addition to these offices, Thermo Fisher Scientific maintains a network of representative organizations throughout the world.

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