



ALK-Abelló Selects Clinical Trial Management System from BSI

By year-end 2010, BSI CTMS shall replace the traditional trial planning & management currently used by trial staff and associates in the allergy therapeutic area.

Baden (CH)/Copenhagen (DK)/, 6th May 2010 – ***BSI Business Systems Integration AG (BSI) wins another customer for its Clinical Trial Management System (CTMS). BSI CTMS will be used by the global leader for allergy vaccines, ALK-Abelló, to replace their current traditional trial planning & management practices of clinical trials. The BSI solution depicts the complete study process, down to the individual patient level. With BSI CTMS 100 users around the world have online and offline access to the forms, reports and compiled data series. What's more, BSI CTMS supports users in the planning and execution of monitor visits as well as budget planning and controlling. Company management receives a transparent view of the status and progress of individual trials. ALK-Abelló is actively involved in the development of functionalities for BSI CTMS. The rollout is planned for the end of 2010.***

Clinical testing of new medicinal products is a business-crucial process for pharmaceutical companies. The faster a company can get approval for a new medicine, the longer it can profit from patent protection and therefore the more turnover can be generated with it. BSI CTMS contains all functional modules needed for planning, executing and management of clinical trials. The modules can be flexibly combined which makes it possible to manage local, regional and global trials. Clinical and trial administrative data from investigators, monitors and other trial stakeholders can be managed; overview of inventory and the ongoing financial operating costs can also be monitored. A Process Wizard guides the monitor visit process and the automatic, adjustable visit schedule (author, time, data entry type and modification) enhances efficiency and also ensures the institutional knowledge building of executed trials. The offline version of BSI CTMS makes it possible to enter data directly at the source, such as in doctors' offices. Data migrates to the BSI CTMS central database by means of data synchronization. BSI CTMS, with its open technologies and architectural concepts, such as Java, SOA and XML, flexibly integrates with existing IT environments and applications.



Intuitiveness supports staff with their core duties

BSI CTMS has existed since 2007. The application is based on BSI's proven CRM system and is appreciated – as is the CRM solution – by pharmaceutical companies for its intuitive user interface. “Simple interfaces keep training costs down and reduce the risks of inaccurate entries and system rejection. It enables staff to concentrate on their core duties; entering and administrating of trial data,” says Jan Nielsen, BSI Project Manager.

Faster time-to-market and more efficient use of resources

The main goal of software-supported trial planning and management at ALK-Abelló is to enhance efficiency of resources and improve communication. BSI CTMS will assist the company by integrating trial procedures in a standardized and regional way, and then enabling the direct entering of progress information into the CTMS. A further added value to ALK-Abelló by using BSI CTMS is the simplified coordination of trial execution, such as budget planning and controlling, and the planning and monitoring during trials at patient level.

Management also profits from the new clinical trial management system: BSI CTMS provides an overview at any time of ongoing and planned trials as well as the status of those already completed. “This means that we can not only implement and use existing resources more effectively, but also future resources. Status reports of trials can be generated at any time, providing us with reproducibility in trials, which in turn helps support us when working with trial partners and authorities,” noted Martin Rud Pedersen, Director of Clinical Development at ALK-Abelló.

Pictures as well as a factsheet are available at: http://www.gcpr.de/1-1_en/bsi_ALK_06052010.html.

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We develop software at the interface to the customer

BSI CTMS is an innovative solution for clinical trails in the pharmaceutical industry. BSI CRM is the leading Swiss solution for any relationship and any task, such as sales, marketing, service and multichannel contact centers. BSI Counter is the product for clear processes at counters and cashiers. The simplicity and versatility of our software has already convinced more than 70,000 users. Actelion, ABB, APG, Commerzbank, Hermes Logistik, Holcim, Landis+Gyr, PostFinance, PricewaterhouseCoopers, Roche, the Swiss Post, Sika, Swiss Life, Tamedia, Viseca and other market leaders all rely on BSI products. We are specialized in system integration, software development, consulting and support services. Service-oriented architecture (SOA) means that our solutions can be integrated into any IT landscape.

About ALK-Abelló

ALK's mission is to improve the quality of life of persons with allergy by developing pharmaceutical products that target the actual cause of allergy – a unique treatment that induces a protective immune response which reduces and potentially halts the allergic reaction. Allergy vaccination is traditionally administered as subcutaneous injections or sublingual droplets but in 2007 ALK launched the world's first tablet-based vaccine, GRAZAX®. ALK has entered a strategic partnership with Merck regarding the tablet programme in North America. ALK has approximately 1,500 employees with subsidiaries, production facilities and distributors worldwide. The company is headquartered in Hørsholm, Denmark, and listed on the NASDAQ OMX Copenhagen A/S.