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By: [DSG Inc.](#) via [Business Wire News Releases](#)

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## Human Genome Achieves Lupus Drug Goals With DSG's EDC



Human Genome Sciences (HGS: NASDAQ: HGSI) announced that BENLYSTA™ met the primary endpoint in BLISS-52, the first of two pivotal Phase 3 trials in patients with serologically active systemic lupus erythematosus (SLE). These results show that BENLYSTA™ has the potential to become the first new approved drug in decades giving hope to people living with systemic lupus.

DSG supports HGS on four global Phase 3 studies concurrently, providing data capture and supporting data management through its function rich eCaseLink™ EDC software.

“Our clinical trial data management and collection process is essential in a large and complex Phase 3 trial. DSG’s technology leadership and project management ensured that our subject data was accurate, complete and timely,” said Pierre Verroye, Executive Director of Clinical Data Management and Clinical Programming, HGS. “This was our first experience with EDC and DSG really helped lead the way. During the live study, DSG solved emerging, unprecedented challenges through innovation and by adding completely new functionality to HGS’ system. Sites and CRAs gave us a lot of positive feedback about the eCaseLink™ system.”

The study included nearly 400 electronic case report forms per subject, which were highly complex in design and had nearly 1,200 edits per screen. DSG provided critical data reporting tools based on study requirements, allowing HGS data management personnel to continually monitor and efficiently insure data quality.

HGS used DSG's proprietary Data Management Dashboard within eCaseLink™ to rapidly identify any outstanding items needing attention during the global database lockdown. The DM Dashboard, developed with HGS to fill their unique needs won the 2008 Society for Clinical Data Management (SCDM) Data Driven Innovation Award and is now an integral part of DSG's eCaseLink™ product.

DSG software allowed HGS to integrate a licensed Clinical Trial Management System (CTMS), and a third-party Interactive Voice Response System (IVRS) with eCaseLink™, ensuring an efficient and timely exchange of critical information.

"We are extremely pleased and excited to hear that HGS continues to make headway toward controlling SLE and has placed its faith in the technology and experience of DSG. We feel very proud not only being associated with this success but also for being a critical part of its success," said Tony Varano, CEO, DSG, Inc. "DSG currently supports HGS with our global experience and presence on four Phase 3 studies concurrently with eCaseLink™ software. It's very satisfying to solve such a complex problem with such a high level of technological sophistication and support service. The end result is a database lock that went very well and according to plan."

### **About Systemic Lupus Erythematosus**

Systemic lupus erythematosus (SLE) is a chronic, life-threatening autoimmune disease. Approximately five million people worldwide, including approximately 1.5 million in the United States, suffer from various forms of lupus, including SLE. Lupus can occur at any age, but appears mostly in young people ages 15 to 45. About 90 percent of those diagnosed with lupus are women. African-American women are about three times more likely to develop lupus, and it is also more common in Hispanic, Asian and American Indian women. Symptoms may include extreme fatigue, painful and swollen joints, unexplained fever, skin rash and kidney problems. Lupus can lead to arthritis, kidney failure, heart and lung inflammation, central nervous system abnormalities, inflammation of the blood vessels and blood disorders. For more information on lupus, visit the Lupus Foundation of America at [www.lupus.org](http://www.lupus.org), the Lupus Research Institute at [www.lupusresearchinstitute.org](http://www.lupusresearchinstitute.org), the National Institute of Arthritis and Musculoskeletal and Skin Diseases at [www.niams.nih.gov](http://www.niams.nih.gov), or Lupus Europe at [www.elef.rheumanet.org](http://www.elef.rheumanet.org).

### **About Human Genome Sciences**

The mission of HGS is to apply great science and great medicine to bring innovative drugs to patients with unmet medical needs. The HGS clinical development pipeline includes novel drugs to treat hepatitis C, lupus, inhalation anthrax and cancer. For more information about HGS, please visit the company's Web site at [www.hgsi.com](http://www.hgsi.com).

### **About DSG**

DSG Inc. supports clinical trial data collection and management with innovative technology solutions including Electronic Data Capture with specialized Clinical Data Management services, Electronic Patient Diaries, Clinical Trial Management Systems and digital on-demand Case Report Form publishing management software. DSG's products allow user-friendly, accurate and efficient data capture at any investigator site regardless of the technological infrastructure. DSG has successfully supported over 800 clinical trials for more than 325 companies at over 18,000 sites in over 68 countries. Founded in 1992, DSG is a global company headquartered in Malvern, Pa., with additional offices in the U.S., Japan and India. For more information, please

visit [www.dsg-us.com](http://www.dsg-us.com).

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