



## **100% EDC, A Necessity.**

From "Is 100% EDC Realistic?" presented by Suzanne Lamerand of [DSG, Inc.](#) at the 2009 [SCDM](#) Annual Conference, 2009.

The pharmaceutical and device industry faces a hostile litigious and regulatory environment. This current climate can stifle research and, as a result, impede progress that could improve the healthcare of all Americans. The concern is over a new level of scrutiny aimed at pharmaceutical and medical device companies. The good news is that the industry can employ existing technologies to head off potential problems and dramatically reduce risk. That technology is EDC.

After a wave of criticism about the way federal drug regulators are performing their duty, a Supreme Court majority handed down a decisive endorsement of lawsuits in state courts to address deficiencies at the national level. Specifically, lawsuits that claim drugmakers have not given doctors and patients sufficient warnings about side-effects. The six Justices who upheld a verdict of nearly \$6.8 million against a major pharmaceutical company have sent a warning to the industry, and to the Food and Drug Administration. The Court has asserted that the FDA, among other measures, needs to police the industry more closely.

In this current environment, the debate over whether EDC is 100 percent realistic really is the wrong question to ask. The life sciences industry faces tough choices for both clinical trial data management and the post marketing studies regarding these drugs and therapies. In short, the future scrutiny of the clinical trial process could lead to a decline in research and development by industry and the pulling from the market of existing drugs for fear of legal ramifications.

The ramifications of this ruling are clear; the FDA will likely want to see more transparency in the clinical trial management process. Only EDC can provide such assurances. Paper-based methods run the risk of loss or improper auditing and management of CRFs. By moving to 100 percent EDC, companies will better track data, manage study information and, at the end of the day, be better protected against future law suits proclaiming that the study process failed to account for any severe adverse reactions or possible complications. This not only applies to drug companies, Congress is considering placing the same requirements on medical device companies as well.

Industry is at a critical juncture. While no system can ensure that new drugs and therapies will be without risk to the patient, EDC is the most available and proven insurance policy organizations can use to protect themselves now and in the future.

100 percent EDC, conducted properly, will help to create an environment that continues to innovate. Which benefits us all in the end.