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**BIG DATA DEAL**

**GSK to Open Clinical Files**

With news about big data, Aetna, Covance, GNS, Scrip, Quintiles, PPD, Icon, BioClinica, Merge, Medidata and GSK.

**WITH FDA IN SERBIA**

**Korea Deal For Parexel**

With news about FDA, CTMS, PMG Research, Inclinix, EMA, Hemofarm, Parexel and the Korea Drug Development Fund

**PROFILE: QUANTICATE**

**Does Clinical Data Matter?**

David Underwood of Quanticate says some firms are giving short shrift to the basics of clinical trials

**ROCHE SAFETY LAPSE?**

**Internal Surveillance At FDA**

With news about Roche, Quintiles, Allscripts, Janssen, SGS, Oracle, TriReme, OpenClinica and FDA



MONDAY NEWS

**Amgen Safety Worries**

AUGUST 17, 2009

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**Human Genome Sciences** is using the electronic data capture (EDC) solution from **DSG** in four Phase III trials. One recent trial had 400 unique case report forms for each subject. Said Pierre Verroye, executive director of clinical data management at Human Genome Sciences: "DSG solved emerging, unprecedented challenges through innovation and by adding completely new functionality to HGS' system. Sites and clinical research assistants gave us a lot of positive feedback about the eCaseLink system."

There are significant inaccuracies in many blood test strips and meters that diabetics use. Concomitant medications taken by diabetic individuals can selectively raise reported blood sugar levels, leading to misdosing of insulin. The companies involved include Abbott, Roche, Smiths Medical, Insulet and Home Diagnostics. There have been 13 deaths to date. Here's a [wire service story](#) and [an FDA warning](#) to the medical community.

To invest in the energy and junk food industries, the **Bill Gates charity** has unloaded stakes in pharmaceutical companies, including Abbott, Johnson & Johnson, Lilly, Pfizer, Schering and Wyeth. Here's a [wire service story](#).

A physician in Pensacola, Florida, has been forced out of his county-level public health position by area politicians. The offense? Using billboards to draw attention to unhealthy eating habits. Don't mess with **Dunkin' Donuts**, folks. Here's a [USA Today story](#).

It's a provocative idea. Is the experience of browsing the cluttered, messy internet destined to be less productive—less pleasant—than tapping an iPhone [web application](#) that does *one* thing well? That seems to be [Luke Wroblewski's](#) point.

We neglected to mention it at the time, but **IBM's** recent \$1.2 billion acquisition of **SPSS** could have implications for the pharmaceutical technology landscape. IBM contends the business analytic software industry is a \$25 billion market. SPSS, meanwhile, specializes in data mining and visualization. "We are extending our capabilities around a new level of analytics that not only provides clients with greater insight—but true foresight," said Ambuj Goyal, IBM's general manager, information management. "Predictive analytics can help clients move beyond the sense and respond mode, which can leave blind spots for strategic information in today's fast paced environment—to predict and act for improved business outcomes." The SPSS website has some abbreviated examples of what customers do in research and hospital environments, including an Australian [case history](#) in which ditching paper records helped a hospital manage back pain patients.

**Amgen** is the subject of **Business Week** and **BioWorld** articles. Amgen's osteoporosis and oncology candidate, **denosumab**, was reviewed by an FDA advisory committee last week. Expectations for the monoclonal antibody seem to be falling despite solid efficacy data. The issue is safety. As a result of such concerns, it is likely there will be a risk management plan or label warnings or both. And physicians are already saying that generic drugs may have better safety profiles and lower costs.

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