



## MAJARO and SAS TRANSFORM CLINICAL DATA MANAGEMENT

SANTA CLARA, CALIFORNIA – March 30, 2004 – MAJARO InfoSystems Inc., developer of ClinAccess™ the leading SAS® powered clinical trials system, today announced support for SAS® 9. Pharmaceutical, biotechnology, and medical device companies face the daunting challenge of collecting years of data from thousands of patients in order to demonstrate the safety and efficacy of their products, before obtaining marketing approval from the U.S. Food and Drug Administration (FDA) and from regulatory agencies worldwide. The ClinAccess™ suite of products, built upon the SAS platform, delivers simple, cost effective, and rapid clinical trials intelligence to bring new drugs and medical devices to market.

SAS 9 provides a single, scalable platform for delivering proven predictive analytics. These capabilities have long made SAS the product of choice for analyzing the mountain of data collected in clinical trials of new drugs and medical devices. MAJARO's ClinAccess clinical data management solutions harness the power of SAS 9 to reduce both the cost and complexity of collecting, entering, cleaning, and managing clinical trials data. ClinAccess also includes a unique suite of reporting and information access interfaces to aid Clinical Research Associates (CRAs), medical monitors, regulatory affairs personnel, and others responsible for conducting and monitoring clinical trials.

## ClinAccess™ consists of three products:

- ClinAccess/PowerServer™ provides double-key data entry; audit trails; tracking of Case Report Forms (CRFs); query and discrepancy management; autoencoding of adverse events and medications; and reporting, summarization, and graphics tools.
- ClinAccess/CaseBook™ displays images of case report forms side by side with data entry, query resolution, adverse event, and medication coding windows and is the first commercially available system to integrate CRF imaging with clinical data management. Images can be scanned from paper CRFs, received by fax server, or imported from industry standard TIF files. At the end of the trial, the images can be converted to PDF format for electronic submission to the FDA.
- ClinAccess/SureStart™ is an entry level product that provides a cost effective clinical data management solution for companies initiating their clinical trials program.

An Electronic Data Capture (EDC) product is planned for later this year. All ClinAccess products are 21 CFR Part 11 compliant.

The significantly enhanced scalability of SAS 9 ensures ClinAccess customers that their clinical trials system can grow with the enterprise, no matter the size or number of clinical trials managed. "For example, we have one customer who used ClinAccess to manage one of the largest trials ever conducted: nearly 60,000 patients, 2,500 investigators, and 500,000 case report form pages," notes Robert Sturm, MAJARO's Senior Director of Pharmaceutical Applications.

The SAS 9 Intelligence Architecture provides a single environment to both manage and to analyze clinical trials data. Previously, companies might manage their clinical trials data in a traditional operations-oriented database. At the end of the clinical trial, they first had to move their data into SAS and create analysis oriented files, before they could perform the statistical analyses required by the FDA. "The pharmaceutical industry has long wanted a single platform to manage and analyze clinical trials data," reports company President Martin J. Rosenberg, Ph.D. "SAS 9 is that platform and ClinAccess is the product that makes it possible."

## ABOUT MAJARO INFOSYSTEMS, INC.

MAJARO is the leading provider of SAS<sup>®</sup> based solutions for Clinical Data Management. MAJARO's flagship ClinAccess™ product has been successfully employed by pharmaceutical, biotechnology, medical device, and CRO companies of all sizes. MAJARO is also a user of ClinAccess and provides clinical data management and statistical analysis services to the pharma industry.

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## **ABOUT SAS**

SAS is the market leader in providing a new generation of business intelligence software and services that create true enterprise intelligence. SAS solutions are used at more than 40,000 sites—including 90 percent of the Fortune 500—to develop more profitable relationships with customers and suppliers; to enable better, more accurate and informed decisions; and to drive organizations forward. SAS is the only vendor that completely integrates leading data warehousing, analytics and traditional BI applications to create intelligence from massive amounts of data. For nearly three decades, SAS has been giving customers around the world *The Power to Know*®.