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**SAS Institute/FDA Intellectual Partnership for  
Efficient Regulated Research Data Archival and Analyses**

**Presentation at the Leveraging—Collaborating with Stakeholders Meeting  
Duke University, April 12, 2000**

Lee H. Evans, Director  
PharmaHealth Technologies  
SAS Institute Inc.

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## **Abstract**

### **SAS Institute/FDA Intellectual Partnership for Efficient Regulated Research Data Archival and Analyses**

**Presentation at the Leveraging—Collaborating with Stakeholders Meeting  
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**Lee H. Evans, Director  
PharmaHealth Technologies  
SAS Institute Inc.**

SAS Institute desires to form an “Intellectual Partnership” (IP) with the FDA for the purpose of developing and implementing a comprehensive biomedical data framework for medical and biopharmaceutical data submissions. The Institute seeks to work with the Agency to develop new submission data models, piloted through a cooperative demonstration laboratory, to properly deploy analysis-ready scientific data used in regulatory decisions. The imperative of on-line review requires this biomedical data framework be developed with good science and accurate data retrieval and analysis as the guiding principals. Intelligent electronic data management, unified across all aspects of the regulatory process, is vital to achieve the efficiencies and innovations inherent to data-driven regulatory decision making.

The SAS Institute/FDA IP for Efficient Regulated Research Data Archival and Analysis will develop and support integration and interoperability of newly developed standards. This collaboration will combine the expert technical and scientific knowledge of SAS Institute with the expert medical and regulatory knowledge of the FDA.

Throughout the information technology and life sciences industries, promising new technologies and tools will continue to develop rapidly. It is imperative that we work together to concentrate on a strong biomedical data framework that can effectively use these new capabilities to benefit the public health.

## Who We Are

SAS Institute is the world's largest privately held software company. We provide leading-edge, high-quality software solutions to meet the needs of decision makers in business, government, and beyond. A commitment to customer-driven research and development, coupled with strategic alliances with other leading technology vendors, ensures that SAS Institute's customers reap maximum benefits from their investment in SAS software.

Founded in 1976, SAS Institute is in its third decade of double-digit annual growth -- a success fueled in large measure by our ongoing commitment to research and development. Each year, we reinvest almost a third of our revenue in R&D -- a higher percentage than any other software vendor.

Employee and customer loyalty drives our company, producing sustained growth, high productivity, solid profits, and long-term customer and employee relationships. With more than 3.5 million users at more than 31,000 customer sites in 120 countries, we continue to expand both the breadth of our software solutions and the depth of our commitment to our customers and employees.

An example of how SAS software is used is at George Washington University Biostatistics Center is available at:

<http://www.s390.ibm.com/products/s390da/applications/csgwu.html>

## History of SAS Institute

In 1966, University Statisticians Southern Experiment Stations was granted NIH funding to develop general purpose statistical software. I believe the universities were Clemson, Virginia Tech, and NC State; and the developers were Jim Goodnight, John Sall, Jane Helwig, and Tony Barr.

In 1972, the Statistical Analysis System was released for IBM mainframe computers, and NIH funding stopped. The developers wanted to maintain the software. Dr. Goodnight (our President and CEO today) offered to teach for \$1.00 a year and unlimited mainframe computer time. NC State accepted his offer.

The developers continued to maintain and update the statistical software with some funding obtained from USDA. In 1976 SAS Institute was founded and called SAS because the mission broadened beyond the Statistical Analysis System.

While we have broadened our scope, our foundation remains good science and good statistical analysis.

## **Awards to SAS Institute Inc.**

The awards and achievements listed below are a testament to the Institute's technological leadership, and to our longstanding commitment to customers, employees, business partners, and the wider community.

**Fortune magazine's "100 Best Companies to Work for in America"  
1997 & 1998 (#3 Ranking)**

**Association for Women in Communications "Ruth Weyand Award " 1999**

**FEMALE national "Family Friendly Business Award" 1999**

**Working Mother magazine's "Top 100 Companies for Working Mothers"  
1998 (#10 Ranking)  
Also in Top 100 for 10 years running**

**Partners in Quality Award from the U.S. Census Bureau, 1997**

**EVE Award from the U.S. Department of Labor**

## **Awards for SAS Institute Technology**

Data Warehousing	The Data Warehousing Institute 1999 DM Review 1999, 1998 DM Review readership survey 1999, 1998 Software Magazine 1998 Datamation 1996 & 1997
Data Mining	Meta Group 1997 & 1998 Yphise (French software analysts) 1997 & 1998 KDD Cup 1998 FOSE 1998
End-to-End DW	Meta Group 1998 DM Review 1997 & 1998
Decision Support	Intelligent Enterprise 2000 DM Review 1998 Software Magazine 1997 Start Magazine 1998
Technical Assistance	Software Professionals Association for Complex Support 1998, 1997
Open Application	Open Software Foundation 1997
Web, Intranet	Infoweek 1996 InternetWeek & Network Computing, 1998 TMFI, PC Week 1998 Web Marketing Association Inc.
Statistics	Sentry Market Research 1996
EIS / OLAP	Butler Bloor, Xephon etc
Business Information	Human Resource Executive DCI 1998

## Awards given by SAS Institute

### SAS Institute Honors Enterprising Customers

Every year at the annual meeting of SAS Users Group International (SUGI), SAS Institute honors some of its most enterprising customers. The Enterprise Computing Awards have been given in three categories -- commercial, government, and university/research -- to organizations that best illustrate the use of SAS software to meet business goals. An additional category was added to the awards. SAS Institute's 1999 Academic Computing Award (ACA) was presented by Dr. Goodnight, CEO of SAS Institute Inc., to Paul Nicholson of University of Leeds. While it was always satisfying to learn about commercial organizations that are gaining competitive advantage from SAS software, Dr. Goodnight said the achievements that gave him most pride were in the field of medical research. He took great pleasure in presenting the inaugural ACA to Paul Nicholson of the University of Leeds (United Kingdom), which has been using SAS software to track incidents of childhood leukemia.

The University of Leeds' ***Disease Registry Application*** is an application based upon The SAS System® for the analysis of disease incidence data. The application is designed specifically for use by epidemiologists engaged in Descriptive Epidemiology interested in studying the variation in disease incidence rates by age and sex, geographically and over time. Typically data for such investigations reside in disease registries and consist of case counts and other disease-related information, population data and data relating to the geographical boundaries and characteristics of the areas covered by the disease registry. The ***Disease Registry Application*** utilizes a specially developed data model to collate all the data required for analysis. An easy-to-use graphical user interface guides the user in data selection and presents results in the form of tables, graphs and maps.

<http://www.leeds.ac.uk/iss/projects/sas/nicholson.pdf>

## **Related Publications**

For additional information, go to:

[http://www.sas.com/ads/wp\\_form.hspl?code=gov](http://www.sas.com/ads/wp_form.hspl?code=gov)

For information about security on the web, go to Data Mining, and then check on Data Mining Best Practices papers.