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Public Remarks to the Commissioner of the
United States Food and Drug Administration
In Open Hearing at Durham, North Carolina

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

Presentation at Leveraging--Collaborating with Stakeholders Meeting
Duke University, April 12, 2000

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SAS Institute Inc.

On behalf of SAS Institute, a global software company headquartered nearby in Cary, North Carolina, I would like to thank Dr. Henney and her colleagues from the Agency for this opportunity to discuss collaboration to benefit the public health. FDA has eliminated literally tons of paper now that it receives electronic submissions. For the first time, data is part of a submission. SAS has worked closely with the Agency to adopt a submissions standard for data transfer formats. These are important steps in moving towards more efficient data-driven decision making at the agency. But there is room for additional improvement in regulatory information management. Existing technologies offer opportunities to improve the quality and usefulness of electronic data.

My name is Lee Evans, and I am director of PharmaHealth Technologies, a division of SAS Institute that is focussed on developing and implementing technologies to improve the quality and usefulness of electronic data to support decisions in biomedical research.

As each of you well knows, quality regulatory review depends on quality data. The systems to properly deploy that data to audit, review and analyze submissions are vital to proper regulatory decisions.

SAS Institute proposes a partnership with FDA to build a conceptual model for the optimal use of submission data. We further propose a regulatory data sciences laboratory at SAS Institute, with a replicate pilot laboratory at FDA, to demonstrate and validate that conceptual model with the Agency.

First, what can FDA and SAS Institute can do together?
Together we can develop a conceptual model based on good medical, statistical and computer science. The focus of the laboratory should be a framework to reliably serve standardized, analysis-ready data to support regulatory reviewers and their electronic tool set. It will utilize available metadata standards for research data warehousing through electronic portals to support data transfer, review, integration, control and familiarity at the FDA. The conceptual model is tested in the FDA/SAS laboratory to evaluate the human factors as well as the technical design of the system.

Next, how can FDA and SAS make this partnership happen?
We propose to unify data technology experts from SAS with regulatory experts from FDA to develop the conceptual model. These experts can collaborate using SAS Institute's physical facilities, hardware and software, using our technical expertise to staff the data sciences laboratory.

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The benefits are as follows:

- The quality of data-driven review and decisions is assured.
- Reviewers have transparent access to analysis-ready data within and across submissions to make decisions to improve the public health. The mission of the Agency, therefore, is enhanced.
- The industry gets a clear understanding of a common data framework that will be used at FDA to deploy their submissions data to the review divisions.
- SAS Institute gets an opportunity to better serve our important customer, the US FDA, and leverage opportunities for joint education and cooperation between our employees and FDA people to build better technology solutions.

In summary:
FDA and SAS Institute should collaborate on a conceptual model for submission data and demonstrate and refine that model in a controlled laboratory environment. FDA and SAS Institute people can make this happen by using our respective skill sets. The partnership will benefit the public health through better processes for electronic data review.

We propose to meet with the appropriate people at the Agency to plan our collaboration on the data submissions model and the data sciences laboratory as soon as possible. SAS Institute stands ready to take action on this matter, and we appreciate your attention to our proposal.

Call me at 919-677-8000 so that we may arrange a meeting.