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Electronic Submission of Regulatory Information

Public Hearing
December 18, 2006

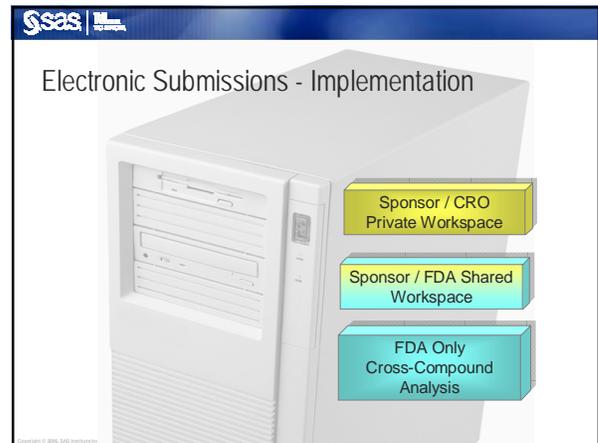
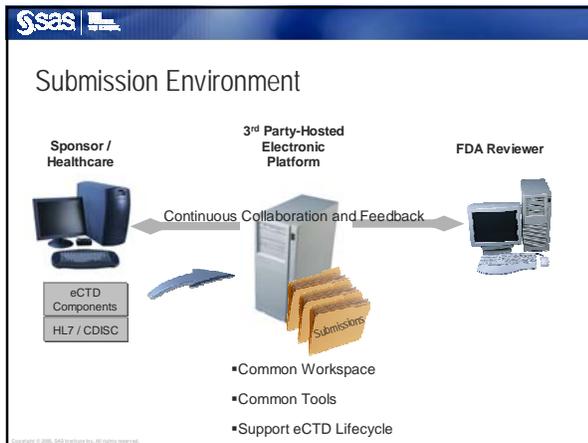
Laurie Rose
Director Health & Life Sciences, SAS

THE POWER TO KNOW.

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Areas of Docket No. 2006N-0464 Addressed by SAS

- Electronic Submissions
 1. Transition from Paper Submissions to Electronic Submissions
 2. Cost
 3. Time
 4. Implementation
- Third Party Entities
- General Observations and Recommendations



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Electronic Submissions - Implementation

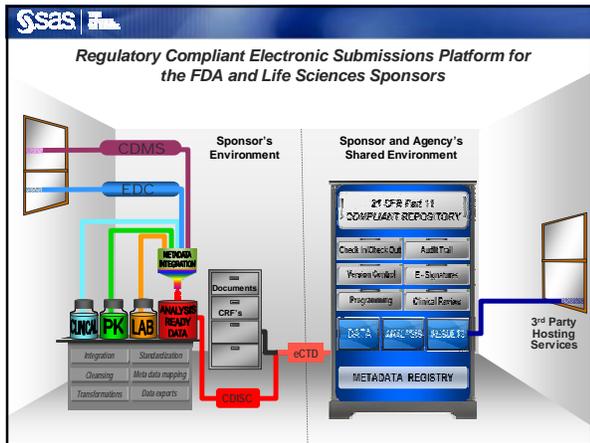
- Cost Minimization – Benefits of Hosted, Shared System
 - Global access 24/7, 365
 - Reduced implementation / support resources
 - Installation / validation by 3rd party
 - FDA IT resources freed for other development



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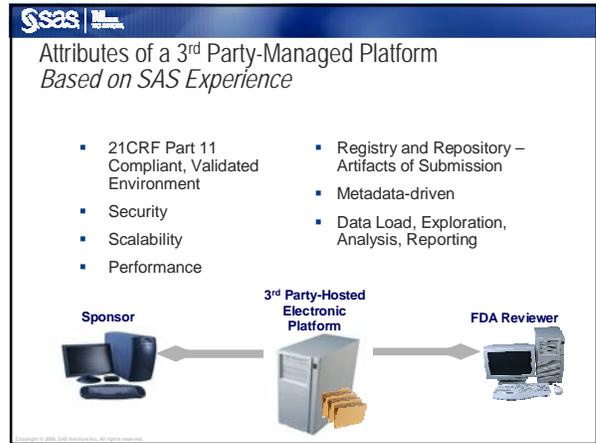
Electronic Submissions - Implementation

- Support for Standards
 - CDISC benefits to sponsors, vendors, FDA
- Tools for Submission
 - Review tools vs. Submission tools
 - CDISC specific tools



- ### Third Party Entities
- General Viewpoints
 - Neutrality
 - Experienced 3rd Party
 - Business Process Modeling
 - Facilitation vs. ownership
 - Process collaboration

- ### Third Party Entities
- Services
 - Implementation and infrastructure
 - Technical support and training
 - Technical services
 - Collaborative Efforts
 - Framework for collaboration
 - Security mechanisms
 - User profiles
 - Change management procedures
 - Policies for governance



- ### Attributes of a 3rd Party-Managed Platform Based on SAS Experience
- Web-based Portal – FDA, Sponsors (and CROs)
 - Integration with Tools and Applications
 - Workflow to Automate Submission Process
 - Support HL7/CDISC Process Flow
 - Provide Common Repository for Cross-Study Review

