



Delivering Clinical Study Data Using SAS/IntrNet

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Introduction

Aims of presentation / demonstration:

- Describe Patient Data Browser and how SAS/IntrNet was employed.
- Business Requirements and Goals
- Technical / Design Considerations
- Demonstrate functionality / ease of use (online demonstration)
- Futures
- Conclusions

Need for the Patient Data Browser

- Newly adopted FDA guidelines:
 - Clinical study data be delivered as SAS® data files in all electronic submissions.
- Increasing speed and depth at which Clinical Scientists need to assimilate this data

Need for the Patient Data Browser

- GlaxoSmithKline utilizing SAS/IntrNet technology has developed a Patient Data Browser to address these needs

Business Requirements

- Pre-Report Delivery
 - A mechanism to:
 - assimilate patient data content
 - obtain a better feel for what SAS® output to expect prior to formal delivery of reports

Business Requirements

- Post-Report Delivery
 - Fast access to patient data
 - Easy identification of data trends surfacing from review of output already provided
- Autonomous method of answering follow-up data requests / reduce dependency on ad-hoc requests

Business Requirements

- Resource
 - Fast browser interface with electronic patient data
 - User friendly browser interface
 - Easy to learn and use

Business Requirements

- Resource
 - Reduce volume of printed output
 - Avoid tendency to use paper output as database

Business Requirements

- Internal Processes
 - Data Browser to fully leverage:
 - Reporting database
 - Reporting toolkit
 - Validated according to GCP

Business Goals

- Improved definition of up-front formal report requests
 - Clinical use of Data Browser leads to a better understanding of patient data
 - Greater understanding of clinical requests since “speaking the same language”

Business Goals

- Remove tendency to request unnecessary reports up-front
 - Avoid building a paper based ad-hoc query tool
 - Remove request of numerous additional reports “just in case” information may be needed later

Technical / Design Considerations

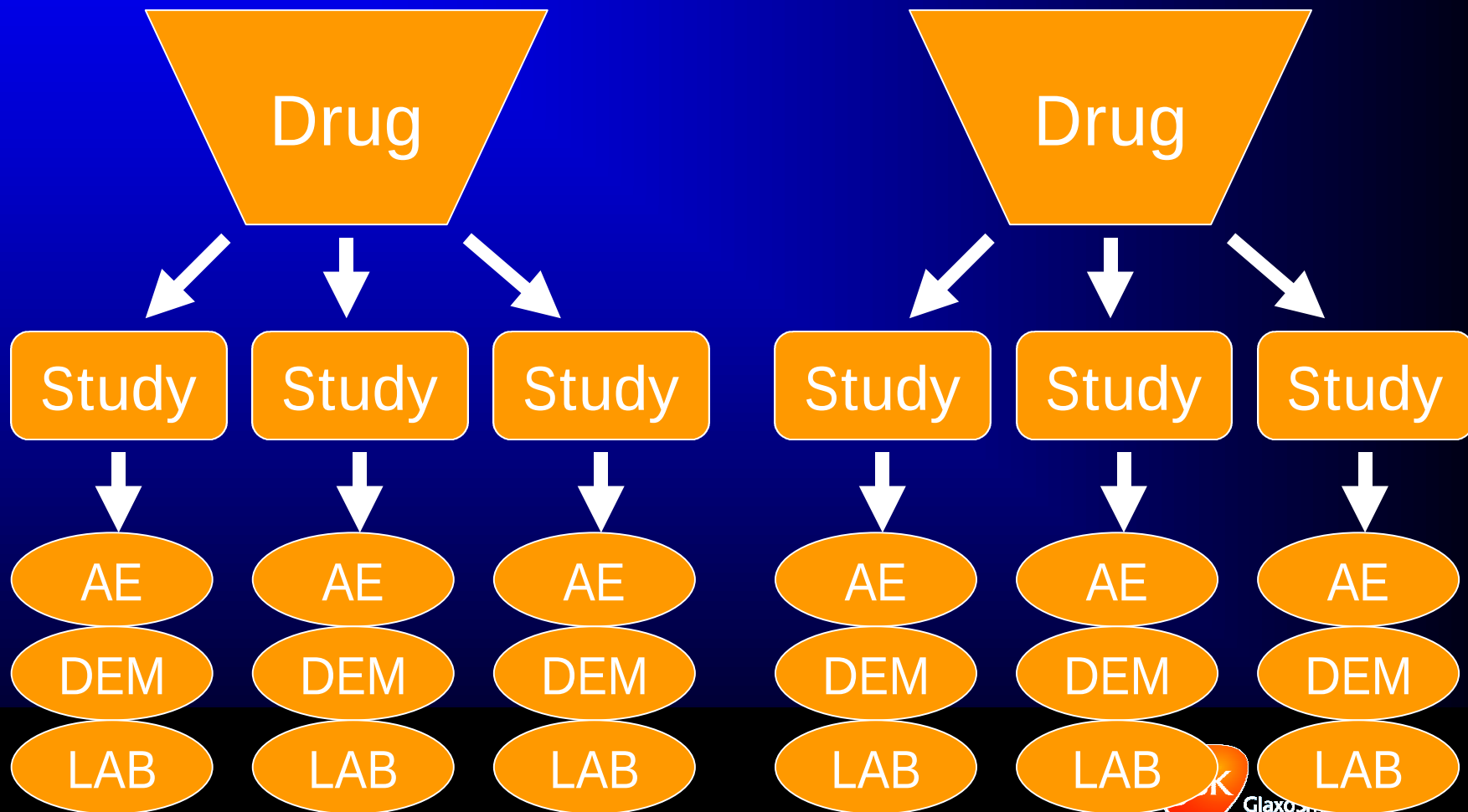
- Make it easy to find study data
 - Conceptual Model

Technical / Design Considerations

Conceptual Model

- Make it easy to find study data
 - Clinical Trial Data organized hierarchically by:
 - Drug
 - Study
 - Data

Drug / Study / Data Hierarchy



Technical / Design Considerations

- Make it easy to find study data
 - Conceptual Model
- **Make it fast**
 - Application Performance

Technical / Design Considerations

Application Performance

- Make it fast
 - Server Processing
 - Wide Area Access
 - Thin Client Web Access
 - Large Data Sets
 - HTML Table 'Chunking' (deliver large data sets as small html tables)
- Provide Subset Function

Technical / Design Considerations

- Make it easy to find study data
 - Conceptual Model
- Make it fast
 - Application Performance
- Make it easy to use
 - User Interface

Technical / Design Considerations

User Interface

- Make it easy to use
 - Simple to Learn
 - Web Browser Interface
 - Preserve Context
 - Status Bar displays Drug, Study and Data
 - Easy Function to Function Transition
 - Tool Bar
 - Isolate Content
 - Display Window separates interface from content

Technical / Design Considerations

- **Make it easy to find study data**
 - Conceptual Model
- **Make it fast**
 - Application Performance
- **Make it easy to use**
 - User Interface
- **Make it easy to maintain**
 - Security and Administration

Technical / Design Considerations

Security and Administration

- Make it easy to secure and maintain
 - Security
 - Certificate Based Security System
 - User Access File (control access to drugs)
 - Drug Registration File (required)
 - Enables access to the drugs, studies and data
 - Allows for descriptive drug names
 - Study Registration File (optional)
 - Enables access to data within a study

Technical / Design Considerations

Overcoming Limitations Of Version 6.12

- **Preserving Process State**
 - Passing of Macro variables from click to click
- **Accessing temporary data sets**
 - Storing temporary files for later reference
- **Character variable length limit of 200**
 - Building links including URLs and macro parameters

On-line Demonstration

Futures

- More sophisticated subsetting & joins
- Upgrade from SAS 6.12 and IntrNet 1.2.
- Refer back to the process ID to recall state will simplify development.
- Longer character data will eliminate hurdles associated with the 200 char limit.
- The ODS system will simplify code generating HTML, XML, PDF,...

Conclusions

Reasons for Patient Data Browser success:

- Easy access to Clinical data
- Easy to learn and use (familiar web interface)
- Fast Performance

SAS/IntrNet is a valuable tool for deploying Web solutions

- Rapid Development and Deployment

We look forward to utilizing new features of Version 8 SAS® and SAS/IntrNet