



COMSYS Clinical



Utilizing the SAS Business Intelligence Platform in a Clinical Trial Environment

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ABSTRACT

Clinical trial environments are rampant with similar tasks being performed over and over again on similar data. The past two decades have seen substantial standardization of data storage and reporting; and as a result the time is right to leverage business intelligence software to maximize the value of these vast warehouses of clinical data. The SAS Business Intelligence platform is a logical path to take because of the easy integration with existing SAS programs and data sources that are already proven and familiar. This will also allow non-traditional SAS users such as statisticians, study monitors, biologists and data managers to access the data without the use of traditional SAS code.

It should be noted that the optimal SAS product for clinical trial projects is SAS Drug Development (SDD). This paper is intended to present an alternative to using only the traditional SAS modules in a clinical trial environment. This is especially useful for companies needing to perform ad-hoc analysis and reporting on their data outside of formal submissions such as validating results from a CRO.

INTRODUCTION

This paper intends to accomplish the following things:

1. Map clinical user groups to BI platform roles and tools.
2. Identify the components of the SAS Business Intelligence Platform and how they fit into the clinical trial process.
3. Provide a brief demonstration of integrating existing SAS Clinical Code into a SAS BI Platform and exploiting it from the different reporting and analysis tools.

4. Outline the value that the SAS Business Intelligence Platform brings to a company that has to analyze and report on clinical data.
 - a. Reduce bottle necks in gaining knowledge from clinical data.
 - b. Widen the audience of users that have direct access to data.
 - c. Allow developers and programmers to focus on building robust data architectures and facilitating data access rather than creating, running and distributing ad-hoc reports/queries.

CONCEPTS

Groups and Roles

The primary value realized when using the SAS BI platform is the empowerment of users to extract their own information from the data while eliminating dependencies on designers and administrators. The designer and administrator groups should be focusing on improving application and data architecture rather than responding to report and analysis requests.

When considering a business intelligence tool purchase and implementation, it is important to assess your current user base and document their preferences and needs. Having these types of details gathered and documented will be beneficial during the implementation and training portion of the platform roll out.

Table 1 below maps typical business intelligence roles to typical clinical study roles. Depending on the experience and background of the clinical team at your company, this may need to be modified for your site.

Table 1. Clinical Roles Mapped to BI Roles

BI Role Tool	Clinical Role
Administrator SAS Management Console	IT Administrator SAS Administrator
Developer/Power User SAS Management Console SAS Enterprise Guide SAS Stored Processes SAS Information Map Studio	Data Architect Data Integrator SAS Application Developer SAS Programmer Statistician
Consumer SAS Add-in for Microsoft Office SAS Web Report Studio SAS Information Delivery Portal	Data Manager Investigator/Monitor Medical Writer Director or Manager of Biostatistics

SAS Business Intelligence Platform Components

- SAS Management Console**
 The SAS Management Console allows IT and SAS administrators to implement and monitor the SAS BI Platform and appropriate security settings to the SAS BI environment.
- SAS Enterprise Guide**
 SAS Enterprise Guide is a user friendly graphical user interface to the SAS programming language. Users can use project palettes to browse, analyze and report on data. Users can also convert their project to a stored process very easily to share with other information consumers.
- SAS Stored Processes**
 SAS Stored Processes are essentially SAS programs which have a wrapper on them. This wrapper consists of a few lines of code at the beginning and end of the program. If the program is a macro, the parameters can be easily set up as parameters automatically presented in a graphical user interface.
- SAS Information Map Studio**
 Information Map Studio allows clinical data set designers to map physical data structures to business data structures and definitions that are ready for analysis and reporting. Information consumers and analysts can use this data without having to know the physical attributes of the data.
- SAS Add-in for Microsoft Office (AMO)**
 The SAS Add-in for Microsoft Office allows users already familiar with Microsoft Office products to browse, analyze and report on data. Users can even run existing SAS programs (stored processes) from Excel, Word, PowerPoint or Outlook.
- SAS Web Report Studio**
 SAS Web Report Studio is a thin-client reporting tool. Information consumers only need a web browser on their client machines to be able to browse and report on data. Users can build reports that consist of tables, listings, graphs and stored processes. These reports can then be made public or kept in the user's private folder.
- SAS Information Delivery Portal**
 The SAS Information Delivery Portal provides a common front end for clinical trial information. Think of it as the clinical Yahoo or Google with users able to customize their own "home" pages as well as have access to pages shared by the designers.
- SAS BI Dashboard**
 (special portlet within the SAS Information Delivery Portal)
 The SAS BI Dashboard enables users to monitor their key measures in a dashboard format. SAS BI Dashboards are created, maintained and viewed via the Information Delivery Portal. Some examples of key measures that could be tracked on a SAS BI Dashboard are # of data discrepancies (failed edits), # of patients enrolled or at a certain point(visit) in each study, percentage of types of adverse events experienced per drug arm, etc.

Figure 2. Overlaying the SAS Business Intelligence Tools onto a Typical Clinical Study Process

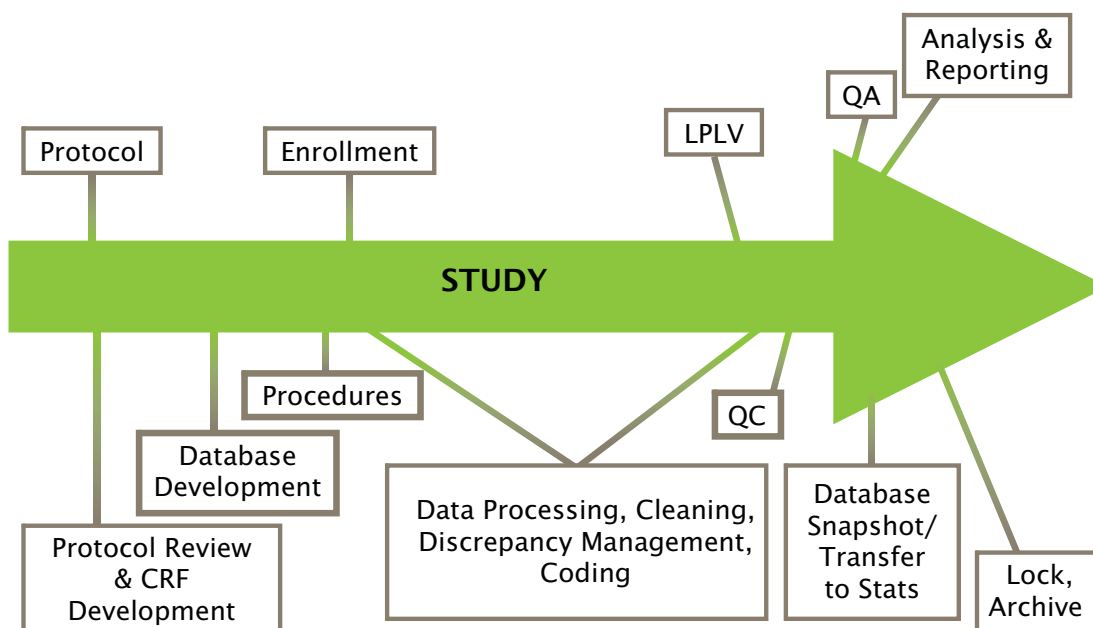


Figure 2 outlines a typical clinical data management process. Of course these can vary slightly based on the type of study or company involved, it is fairly representative. By using the SAS BI platform, the following areas of the above process flow can be accomplished more efficiently.

Data Processing, Cleaning, Discrepancy Management, Coding

Relational database tables can be registered as libraries in the SAS Management Console. This will enable the developers and power users to make the data available to the information consumers in such a way that the consumers don't need to know the physical attributes of the data or how the data is joined together. The data architects, data integrators and SAS programmers design and implement a consistent efficient structure so there are not unnecessary copies of data all over the servers or desktops. Many inefficient queries can also be avoided because only the team members that are experts with the data architecture and the SAS BI platform are controlling the query construction.

The members of the developer/power user team can also design "canned" reports to demonstrate data consistency and cleanliness. Although the information consumers will be able to design their own discrepancy checks, many of the standard ones can be wrapped up in one or more SAS stored processes or designed as SAS Web Report Studio reports.

Quality Assurance (QA)

Using the SAS BI platform will reduce the manual effort required for producing discrepancy management reports as well as custom data queries. The clinical data is available to the information consumers via SAS Web Report Studio, the SAS Add-in for Microsoft Office or Enterprise Guide. The choice of tool(s) for surfacing reports and queries will depend on user preference and connection into the network. For example, a company may only want their investigators and study monitors to use a web browser.

When the architecture and tools allow information consumers to access their own data without understanding how to code queries or join tables together, they can focus on reviewing and cleansing the data.

Analysis and Reporting

Using the SAS BI platform for clinical analysis and reporting can result in the similar benefits as the QA effort. Running existing reports and/or creating new reports can be accomplished via a web browser or through thicker clients such as Enterprise Guide or Microsoft Office products. All queries that are supporting reports and analysis are controlled by the SAS Metadata server so consistency is achieved for background processing.

CONCLUSION

As one can see, there are many advantages to utilizing the SAS Business Intelligence Platform in a clinical environment. One significant benefit realized is the ability for non-developers to access information and make decisions without having to request the time of a programmer/analyst or data architect. In addition, existing SAS Macros can easily be converted to stored processes which can be run from MS Office or Internet Explorer, thus leveraging the code already in place.

REFERENCES

SAS BI Administrator and Usage Documentation

Society for Clinical Trials 2007 "Essentials of Clinical Data Management"

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Your comments and questions are valued and encouraged. The authors may be contacted at:

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