

PharmaSUG 2007 Seminar Offerings

We have some exciting seminars scheduled for this year covering a variety of topics and taught by some leading experts to enhance your conference experience! Half-day seminars will be offered on Saturday and Sunday, morning and afternoon, Wednesday afternoon, and one all day Thursday. A box lunch will be provided to the Wednesday afternoon seminar attendees at no cost and am/pm snack breaks will be provided during all seminars.

All half-day seminars cost \$99 each, the same as last year! Thursday's full day seminar cost is \$198 and lunch is on your own; all seminar costs are in addition to the conference registration fee. Each seminar attendee receives course material and a seminar completion certificate.

Space is limited, so sign up early as soon as conference registration opens online when you register for the conference. **Please read the seminar descriptions below very carefully before you register and be sure to make a copy of your conference registration form to keep for your records.**

SEMINAR REGISTRATION, ATTENDANCE AND CANCELLATION POLICY

1. You must register for the conference in order to attend seminars.
2. You must register for a seminar via the PharmaSUG 2007 conference registration form either by postal mail, fax, or online.
3. If after registering for a seminar, you find you cannot attend, you may ask another conference attendee to take your place as long as you notify the Conference Registrar (Margaret Hung) and a Seminar Coordinator (Diana Williams or MaryAnne Hope) in advance.
4. You may cancel a seminar prior to May 4, 2007 and receive a full refund minus a \$25 administration fee per cancelled seminar.
5. Prior to May 4, 2007, you may swap one seminar for another; however, this is a conference registration change and will incur a \$25 administration fee.
6. After May 4, 2007, you **MAY NOT** swap seminars; however, a new seminar may be added depending on availability.
7. **There will be NO REFUNDS after May 4, 2007.** However, if you can not attend, the seminar material can be mailed to you without additional charge.
8. On-site registration will be permitted based on availability and payable by cash or major credit card (MC, VISA, Discover, AMEX).

For questions please contact Diana Williams at dianasunset@earthlink.net or (919) 929-5015 (weekdays) or MaryAnne Hope at MHope@hsag.com or (602) 745-6312 (weekdays).

Continue to check this web site for more news and information about PharmaSUG 2007 Seminars. There will be one or two SAS instructor taught half-day seminars announced very soon!

PharmaSUG 2007 Seminar Offerings

Building Dynamic Programs and Applications Using the SAS® Macro Language by Art Carpenter (CA Occidental Consultants)

Intended audience/Pre-requisite: SAS programmers/Good working knowledge of SAS Macro Language

Course material: Detailed course workbook

Seminar Description: This half-day seminar shows you how to take advantage of SAS Macro Language capabilities that enable you to write dynamic programs and applications. By mastering the concepts and techniques presented in this class your programs will become free of hard-coded data dependencies, thus eliminating the need to re-write the code every time a data set name, variable name, or other data attribute, changes. Let “them” change the project's specifications as often as “they” want...your code is ready!

The dynamic programming techniques that you will learn about during this seminar:

- are flexible and are easily adaptable to changing data structures, data table names, and variable (field) attributes
- reduce maintenance requirements by removing data dependencies from within programs
- provide significant resource savings during application development cycles
- gives the end-user extensive control over program execution by using tables such as SAS data dictionaries, SAS data sets, and Excel tables
- reduce program validation efforts by providing reusable and generalized code that can be applied to many different applications
- establish controlled data environments, thus insuring data integrity throughout your organization

This seminar makes extensive use of example macros that have been gathered from real world applications, and it concentrates on the techniques necessary to make effective use of these tools.

Manipulating Data with SAS Functions by Ben Cochran

Intended audience/ Pre-requisite: SAS Users from Novice to Intermediate/None

Course material: Textbook consisting of over 150 pages

Seminar Description: This half-day seminar explores the area of data manipulation and shows attendees how to accomplish this through using the myriad of functions provided by the SAS® System. Examples range from simple to complex so that students will learn a lot about SAS Functions regardless of their background. The presentation and textbook have been updated to include SAS9 functions.

Seminar topics will include:

- Introduction to Data Manipulation
- The Structure of SAS Data Sets
- Processing Data with the SAS System
- Introduction to Functions
- Manipulating Numeric Data
- Manipulating Character Data
- Data Conversion
- Other Very Useful Functions

PharmaSUG 2007 Seminar Offerings

Using SAS Dictionary Tables and Views by Frank Dilorio

Intended audience/Pre-requisite: Programmers and application developers/ Working knowledge of SQL and the SAS Macro Language

Course material: Course notes, and access to programs and other materials on Frank's Web site

Seminar Description: Have you ever needed an easy way to determine the number of observations in a data set? Have you ever wanted to programmatically determine whether certain text is in a title or footnote? Do you wish SAS provided you with other information about data sets, options, and features of your programming environment? If your answer to any of these questions is an emphatic (or weary) "Yes!", then this half-day seminar will be an important addition to your SAS programming toolbox.

SAS Dictionary Tables are metadata containing a vast amount of information about the programming environment. These Tables are well organized, have enough quirks to have "character," are automatically created and maintained by SAS, and always present in any SAS batch or interactive session.

This seminar will tour the Tables and demonstrate how they can be used to build robust, powerful utility programs and applications by:

- Demonstrating how to view and access the tables
- Presenting an overview of the tables, emphasizing their relationships
- Reviewing the content and structure of some of the more commonly-used tables
- Showing examples of table use

The quality, reliability, and development speed of utilities and applications can be greatly improved if developers are aware of the complementary nature of Dictionary Tables and other forms of metadata. To that end, part of this seminar will present examples of Dictionary Tables used as an adjunct to other forms of metadata.

Exploratory Graphical Data Analysis in Model Building and Prediction by Prof. George C. J. Fernandez

Intended audience/Pre-requisite: Biostatisticians, data analysts, predictive modelers, statistical consultants/Basic statistical and SAS programming skills

Course material: Hard copy of the full set of power point slides and unlimited access to use of the online SAS macro applications (REGDIAG, and LOGISTIC) covered in this seminar

Seminar Description: Data exploration and graphical data analysis methods stress visualization to thoroughly study the structure of data and to check the validity of statistical model fit to the data. This half-day seminar will cover the fundamental concepts for understanding and successfully applying data exploration and graphical data analysis methods by using the powerful, user-friendly SAS macro applications. Attendees will learn to use partial regression plots, VIF plots, model selection methods based on AICC and SBC, model prediction, regression diagnostic checks, model validation methods used in multiple and logistic regression and partial delta logit plots, best candidate model selection methods, model prediction statistics, diagnostic checks, model validation methods, ROC curve, classification table, and goodness-of-fit statistics in logistic regression models.

The user-friendly SAS macro approach presented in this seminar integrates the statistical and graphical analysis tools available in the SAS system. Using this macro approach, attendees may effectively and quickly perform data analyses, and spend more time exploring data and interpreting graphs and output, rather than debugging their programs.

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Merging, Combining and Subsetting SAS Data Sets (Tricks, Traps, and Techniques) by Malachy (Mal) J Foley

Intended audience/Pre-requisite: Basic knowledge of SAS data step

Course material: Hard copy of power point presentation

Seminar Description: This half-day seminar will discuss over 30 common errors in merging, combining, or otherwise manipulating data. All of these errors result in erroneous data. Most occur with no SAS error message or warning! In addition to examining errors, we will cover a wide range of topics such as interleaving, subsetting, concatenations, the IN= data set option, BY groups, FIRST.variable, program data vectors (PDV), finding duplicate records, collapsing files, overlapping variables, random access, Cartesian products, one-to-one merges, match merges, and fuzzy merges.

This seminar starts with the basics and continues to build to complex, tricky examples of data set manipulation. The only prerequisite is a working knowledge of the SAS DATA Step. Yet, this workshop will give even intermediate and advanced programmers a great review and some surprises too. Come see what mysteries lurk in manipulating SAS data sets!

Testing and Validating SAS Programs in an FDA Regulated Environment by Neil Howard

Intended audience/Pre-requisite: Managers, programmers, analysts, validation programmers, statisticians who program or oversee programmers, database programmers, QC or QA staff/Basic knowledge of SAS

Course material: Binder with copies of slides and worksheets

Seminar Description: This half-day seminar will focus on testing and validating SAS programs, particularly in the context of an FDA regulated environment, with special emphasis on SAS tips and techniques to facilitate the process.

- **WHY:** examination of FDA regulations and guidances; exploration of reviewers' expectations (processes and accountability); implications of audits; and discussion of client requirements and specifications
- **WHAT:** interpretation of guidances; definition of the terms testing, debugging, verification and validation; test plans; and discussion validation items
- **WHO:** accountability in pharmaceutical companies and CROs
- **WHEN:** planning and timing of testing and validation
- **WHERE:** documentation specifics and tips
- **HOW:** SAS and programming tips and techniques [for programmers and statisticians] for debugging, testing, and validation of production and ad hoc code for tables, listings, figures, and derived data sets; syntax, logic, requirements checks; and error handling

The SAS system is easy to use and the learning curve to productivity is relatively short. However, SAS is easy to abuse. Indisputable facts remain in that data is seldom clean, logic is too often faulty, and fingers walk clumsily over the keyboards. Condition codes and a 'clean log' are not always accurate indicators of successful programs.

Since as much as 80% of a programmer's time is invested in testing and validation, it is important to focus on tools that facilitate correction of different types of errors in SAS programs. This seminar focuses on a variety of SAS features, tips, techniques, tricks, and system tools that can become part of your routine testing methodology consistent with 21 CFR Part 11 and other FDA guidances.

PharmaSUG 2007 Seminar Offerings

The Analysis of ADaM Standards by Susan Kenny

Intended audience/Pre-requisite: Statistical programmers and statisticians/None

Course material: Course notes and handouts

Seminar Description: The production of final clinical study reports nearly always requires the creation of analysis datasets to produce many of the summary tables and figures. Whereas, the collected data, as represented in CDISC SDTM, lends itself to definable standards. The derived data, as represented in CDISC ADaM, is not as easily standardized. However, the ADaM model has matured over the last year and is approaching a recognizable standard.

This half-day seminar will delve into the key principles of ADaM as outlined in the published Version 2: Analysis Data Model (V2), and will present the recent advances outlined in the draft ADaM Implementation Guide (IG). A thorough review will include the following:

- Best practices for implementing ADaM within the clinical trial process
- Standard names and value conventions for frequently derived variables
- ADaM specific metadata in the form of analysis dataset metadata
- Analysis value level metadata and analysis results metadata
- Required Subject Level Analysis Dataset (ADSL)

Where possible, these discussions will be accompanied by examples and 'what if' scenarios. The newly drafted Implementation Guide further strengthens the ADaM standard by presenting a standard structure to be used for the majority of analysis datasets. This standard structure and associated metadata will be presented and examples of how to represent analysis issues, such as the creation of endpoint records, the imputation of missing visits, and the use of indicator flag variables will be shown. The implementation of the principles in the IG will be further demonstrated by a metadata review of the ADaM models for linear models (including change from baseline and categorical models), analysis of adverse events, and time to event analysis. Attendees will gain a firm understanding of the principles of ADaM standards and ideas on how to implement them within their processes.

Advanced SAS Graphics by Philip Mason

Intended audience/Pre-requisite: Intermediate SAS programmers/Basic knowledge of SAS Graph

Course material: Handout of Power Point slides and sample code

Seminar Description: This half-day seminar will instruct attendees on how to produce graphics to the precise specification required. The following topics will be explored:

- SAS Graph concepts needed to understand advanced graphics
- How ODS interacts with SAS Graph
- ODS Graphics and the Graphic Template Language
- Getting the required quality, whether high or low
- Techniques to combine multiple graphs and tables
- Getting graphics on the web, including drill down
- Customizing graphics including Data Step Graphics Interface and Annotating graphs

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Using BI Tools from SAS for Clinical Reporting by Greg Nelson

Intended audience/Pre-requisite: Programmers, their managers, and others wanting to understand the capabilities of SAS for Business Intelligence – including SAS Add-in for Microsoft Office, Stored Processes, Enterprise Guide, Web report Studio and the SAS Information Delivery Portal/None required, Basic SAS knowledge (ODS, PROCs and Macro Language) suggested

Course material: Course handout of all presentation materials and examples

Seminar Description: Tables, figures and listings in the clinical world have always been treated like an artisan's affair – each program has to be carefully crafted to fit the requirements of the protocol and while standard macro libraries, program templates and coding standards have been adopted to varying degrees, the convergence on a standard approach to the generation of tables, figures and listings has been fairly elusive.

In this half-day seminar, the attendee will decide by understanding just what the Enterprise BI Server has to offer and included is a tutorial on the creation of Stored Processes for use in SAS Web Report Studio and the SAS Add-in for Microsoft Office. In addition, the use of SAS' Information Delivery Portal will be covered and how all of these technologies fit together.

Advanced ODS by Chris Olinger

Intended audience/Pre-requisite: Report writers and SAS programmers/Basic ODS knowledge

Course material: Handouts and CD of examples

Seminar Description: This half-day advanced ODS seminar will cover topics relating to getting the most out of ODS Styles, reporting techniques using the Base SAS reporting procedures, ODS Tagsets, and using SAS to interface with alternative reporting environments. It will also touch on some of the newer technology coming in SAS version 9.2 such as Statistical Graphics and ODS enhancements to make life just a little easier.

CDISC SDTM Implementation with Real World Applications by Sy Truong

Intended audience/Pre-requisite: SAS Programmers, Managers, Data Managers and Regulatory

Compliance/Basic understanding of SAS programming and standard data structures

Course material: Slides Notes, Quizzes, Sample Exercises and optional sample CD

Seminar Description: Regulatory requirements are going to include CDISC in the near future and the benefits are obvious. It is therefore wise and prudent to implement with techniques and processes refined from lessons learned based on real life implementations.

CDISC standards have been in development for many years. The complexity of clinical data coupled with the technologies involved make implementation of a new standard challenging. This half-day seminar will explore the pitfalls, and present methodologies and technologies that will make the transformation of nonstandard data into CDISC efficient and accurate.

It is important to have a clear vision of the processes for a project before beginning, since projects can push deadlines and break budgets due to the resource intensive nature of this effort. The organization and planning for this undertaking can become an essential first step towards effective implementation. Some of the topics covered in this seminar will include:

- Project Definition, Plan and Management
- Data Standard Analysis and Review
- Data Transformation Specification and Definition
- Performing Data Transformation to Standards
- Review and Validation of Transformations and Standards
- Domain Documentation for DEFINE.PDF and DEFINE.XML

PharmaSUG 2007 Seminar Offerings

Advanced Reporting and Analysis Techniques Used in the Clinical Setting: It's Not Just About The PROCs!

Presented by Art Carpenter in a special full day seminar offering after the conference on Thursday, June 7, 2007. The cost for this seminar is \$198.

Intended audience/Pre-requisite: SAS users and programmers faced with large or complex reporting and analysis tasks, especially if they have a desire to learn more about the sometimes obscure options and techniques used with the advanced analysis and reporting of data/Good solid understanding of Base SAS, especially the DATA and PROC steps

Course material: Detailed course workbook

Seminar Description: There are literally hundreds of techniques used on a daily basis by the users of SAS[®] software as they perform analyses and generate reports. Although often obscure, most of these techniques are relatively easy to learn and generally do not require specialized training before they can be implemented. Unfortunately, the majority of these techniques are used by only a very small minority of analysts and programmers. They are not used more frequently because the majority of SAS users have simply not been exposed to them. Left to ourselves, it is often very difficult to 'discover' the intricacies of these techniques and then to sift through them for the nuggets that have immediate value.

This full day seminar will present a series of those nuggets. It covers a broad range of SAS topics that have proved to be useful to the intermediate and advanced SAS programmer that is involved with the analysis and reporting of clinical data. For most of the covered topics, the seminar will introduce useful techniques and options, but will not 'teach the procedure'.

Included are options and techniques associated with:

- MEANS/SUMMARY
- TABULATE
- REPORT Compute Blocks
- The Macro Language
- Output Delivery System, ODS
- DATA _NULL_
- Operating System Interfaces
- DATA Step Functions and Options

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Seminar Instructor Biography

Art Carpenter's publications list includes four books, and over six dozen papers and posters presented at SUGI, and various regional and local user group meetings. Art has been using SAS since 1976 and is an Advanced SAS Certified Professional™. Through California Occidental Consultants he teaches SAS courses and provides contract SAS programming support nationwide.

Ben Cochran started his own consulting and SAS Training business in the fall of 1996 – The Bedford Group, after more than 11 years with SAS Institute in the Professional Services (as an Instructor) and Marketing Departments (as Marketing Manager for the SAS/EIS product). As an affiliate member of SAS Institute's Alliance Partner Program, Ben has been involved in many teaching and consulting projects over the past 10 years. Ben has authored and presented several papers at SUGI and regional user groups on a variety of topics since 1988.

Frank Dilorio is President of CodeCrafters, Inc. and the author of "SAS Applications Programming: A Gentle Introduction" and "Quick Start to Data Analysis with SAS.", and a SAS user since 1975. A frequent presenter at local and regional user group meetings, Frank has been active in the Southeast SAS Users Group (SESUG) since its inception, co-chairing the 1994 and 1996 conferences and serving one term as the group's President. When not writing about SAS, Frank writes in SAS, focusing on data management and reporting applications in the pharmaceutical industry. In July 2006, Frank was one of nine recipients of the SAS Silver Circle Special Achievement Award.

Prof George C J Fernandez has more than 20 years of experience in teaching applied statistical methods and SAS programming courses. He has won best paper and poster presentation awards at the regional and international SAS conferences. Prof Fernandez has also been invited to present at: ASA meeting in Atlanta (2001), WUSS Conferences: Arizona (2000), San Diego (2002), San Jose (2005), Irvine (2006), MWSUG (2006); 56th Deming's conference: Atlantic City (2003), Sunday seminar (SUGI 2006); Key-note Speaker: 16th Conference on Applied Statistics, Kansas State University. His book on "Data Mining using SAS Applications" (CRC press / Chapman Hall) contains many user-friendly SAS macro-applications.

Malachy (Mal) J Foley is a software engineer and an Independent SAS Programmer/Analyst/Trainer. He is associated with the Department of Biostatistics at the University of North Carolina at Chapel Hill (UNC) where for 10 years Mal was a senior SAS programmer/analyst working with clinical trial data. Moreover, Mal has worked with financial, HR, modeling, engineering, survey and research data for more than 30 years. He holds a degree in Engineering and has several speaking awards from Toastmasters International. Mal teaches at the undergraduate, graduate, and professional levels. He presents papers and gives seminars at local, regional, national, and international SAS users' groups. Mal is the immediate past president of the Research Triangle SAS Users Group (RTSUG) and chaired the Pharmaceutical Industry SAS Users Group Conference (PharmaSUG) in 2006.

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Seminar Instructor Biography (continued)

Susan Kenny is a PhD biostatistician and statistical programmer with over 20 years of experience in public health and clinical trials research. She has been a member of CDISC teams (SDS and ADaM) since their inception in 1999. Susan is the ADaM team lead and was a participant on the first SDTM/ADaM Pilot project. Her interests include developing CDISC implementation strategies during the clinical trial process, especially in the areas of electronic data capture, and using emerging data standards to increase programming efficiencies, and developing programming environments to automate the production of clinical trial reports and integrated submissions. She is currently the Director for Statistical Programming at Inspire Pharmaceuticals.

Phil Mason is well known in the international SAS user community, having written a popular book on SAS Tips & Techniques as well as many papers and courses. He has used SAS continually for 22 years in a wide range of industries, mostly as a SAS Consultant. Phil also spent a year training ten Statistics graduates to be SAS Programmers for a large CRO.

Greg Nelson just celebrated his 20th year in the SAS eco-system. He started out as a Social Psychology student doing statistical analysis, and then quickly moved into applications development. Greg is the President and CEO of ThatWave Technologies where he supports an entire organization focused on helping customers leverage their investment in SAS software.

Chris Olinger, President of d-Wise Technologies, has been developing enterprise software for over 17 years. While employed at SAS Institute he was the manager of the Base SAS reporting group and lead developer of ODS as well as being involved in the design and development of the SAS Drug Development platform. More recently, Chris has been involved in the development of SAS and web based applications within the framework of his own software company.

Sy Truong is the co-founder and president of MXI (Meta-Xceed, Inc.) since 1997. MXI provides software solutions within the Pharmaceutical Industry specializing in CDISC data standards, SAS validation, electronic submission, data analysis, and reporting. Sy is one of the committee members of the Bay Area SAS User Group (www.basas.com). He is a frequent contributor and presenter at PharmaSUG, WUSS, and SUGI conferences. Sy is currently writing a book for SAS Publishing entitled "Becoming a SAS Clinical Trials Programmer".