



PhilaSUG newsletter



Fall 2011 Meeting Announcement

PhilaSUG Fall 2011 Meeting Thursday, October 27th

The Philadelphia Area SAS Users Group Fall Meeting will be on Thursday, October 27, 2011 at 1:00 PM, and will be hosted by Theorem Clinical Research, formerly known as Omnicare Clinical Research. It will be held at the Penn State Great Valley Conference Center, 30 E. Swedesford Road, Malvern, PA 19355. A map and driving instructions are available later in the newsletter.

Registration will begin at 12:15 PM and the meeting will commence at 1 PM. Dues for the year are \$30. There are no other fees for attending PhilaSUG meetings. We will accept cash, but a check is preferred. If you are an employee of our host, fees for this meeting will be waived. A tip – **to breeze through registration** – bring in the completed registration form found in the back of this newsletter to the meeting, otherwise registration can still be simplified if you attach a business card to a check or \$30 exact cash, as there is less writing and it will be more legible. Please do not mail in your registration fee beforehand. Receipts will be available at registration time.



Important - For planning purposes all attendees must complete the Attendance Sign-up form through the PhilaSUG web home page no later than **October 23rd**.

The presenters and the PhilaSUG Executive Committee will adjourn for dinner at a nearby restaurant when the meeting concludes. You are invited to join us. The location will be announced at the meeting

PhilaSUG Fall Meeting	
Theorem Clinical Research	
At Penn State Great Valley	
Malvern, PA 19355	
12:15-1:00	Registration and light lunch *
1:00-1:10	Opening Remarks
1:10-1:30	Caution: Hazards Crossing! Using the Renyi Test Statistic in Survival Analysis, Matthew Davis, M.S.
1:30-2:00	A Regular Language: The Annotated Case Report, Ryan Wilkins
2:00-2:30	From Stocks to Flows: Using Hash objects for FIFO, LIFO, and other FO's, Mark Keintz
2:30-3:00	Break, Posters, and refreshments *
3:00-3:50	ODS Graphics for the Non-Statistician, Cynthia Zender
3:50-4:00	Open Forum
4:00-4:30	What Does Metadata-Driven Processing Actually Mean?, Barry Cohen
4:30-4:35	Closing Remarks

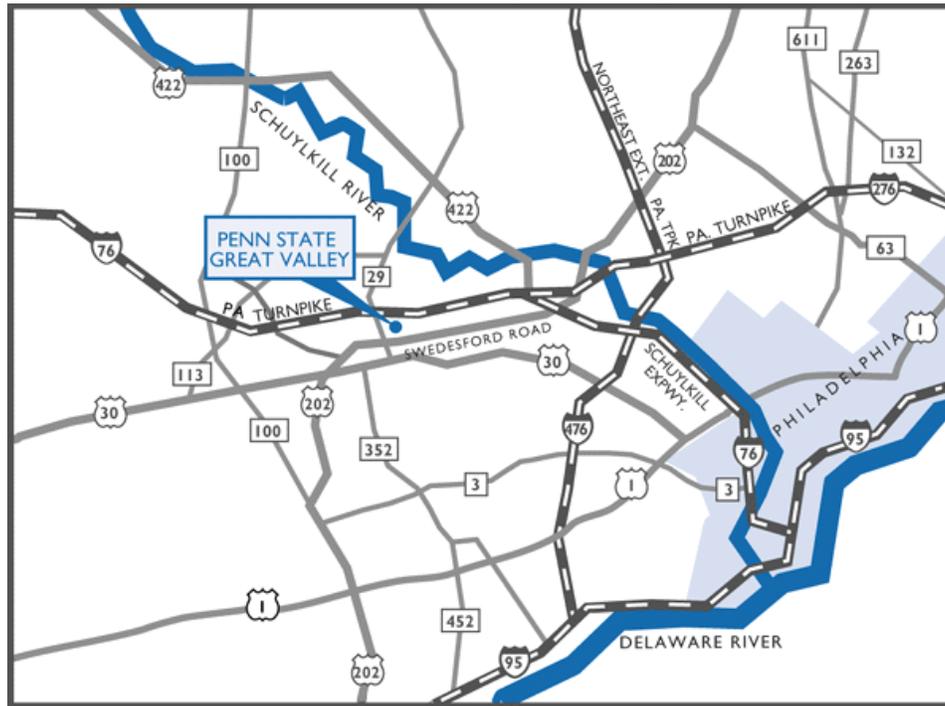
Posters will be on display throughout the meeting. Authors will be present alongside their posters during the break for questions and discussions.

Abstracts and bios are found later in the newsletter.

* Light lunch and refreshments will be provided courtesy of Theorem Clinical Research

Directions to the Meeting Location

The Conference Center at Penn State Great Valley
30 E. Swedesford Road, Malvern, PA 19355



Parking

There is ample free parking in front of both buildings. Parking registration is not required for conference attendees.

From West Chester, Delaware, and South:

1. Take Route 202 North to the Great Valley Exit (Route 29 North).
2. Turn right at the end of the ramp and turn right again at the light onto Route 29 North.
3. Continue to the next traffic light and turn right onto Swedesford Road.
4. Continue approximately 2/10s of a mile to the Penn State Great Valley campus on the right.
5. As you enter the driveway into the campus, the Main Building is on the right, and the Conference Center Building is on the left.

From New Jersey and East

1. Take the Pennsylvania Turnpike westbound to Exit 326 (old Exit 24) at Valley Forge.
2. Follow signs for Route 202 South/West Chester Exit 328 (old Exit 26A).
3. Continue on Route 202 South to the Great Valley Exit (Route 29 North).
4. At the first traffic light, turn left onto Swedesford Road.
5. Then take the first left turn into the Penn State Great Valley campus.
6. As you enter the driveway into the campus, the Main Building is on the right, and the Conference Center Building is on the left.

From Reading and West

1. Take the Pennsylvania Turnpike eastbound to Exit 326 (old Exit 24) at Valley Forge.
2. Follow signs for Route 202 South/West Chester Exit 328 (old Exit 26A).
3. Continue on Route 202 South to the Great Valley Exit (Route 29 North).
4. At the first traffic light, turn left onto Swedesford Road.
5. Then take the first left turn into the Penn State Great Valley campus.
6. As you enter the driveway into the campus, the Main Building is on the right, and the Conference Center Building is on the left.

(continued on next page)

From Philadelphia

1. Follow the Schuylkill Expressway (Route 76 West) to Valley Forge.
2. Then follow signs for Route 202 South/West Chester Exit 328 (old Exit 26B).
3. Take Route 202 South to the Great Valley exit (Route 29 North).
4. At the first light, turn left onto Swedesford Road.
5. Then take the first left turn into the Penn State Great Valley campus.
6. As you enter the driveway into the campus, the Main Building is on the right, and the Conference Center Building is on the left.

Additional directions can be found at <http://www.sgps.psu.edu/about/directions.ashx>

About Our Host



Theorem Clinical Research is a leading global, full-service contract research organization (CRO) headquartered in King of Prussia, Pennsylvania. With office locations in 32 countries, the firm has relationships with customers all across the globe comprised of some of the world's leading pharmaceutical, biotech and medical device companies. Theorem's core CRO services are Early Phase, Phase II/III and Late Phase and the company features specialized Business Units focused on medical device, technical services and pharmaceuticals.

The Biometrics Department at Theorem Clinical Research is honored to host this PhilaSUG meeting. The department has 9 geographic locations in 7 countries using SAS as its primary analysis and reporting tool. Biometrics personnel are involved in all aspects of product development in providing integrated services to client companies in the pharmaceutical, biotechnology and medical device industries. The department has an active commitment to developing their people in learning how SAS is used in clinical trials. As such training takes a priority role within the department as demonstrated by our in-house training modules. The department offers a flexible work policy such that, once an individual's training is well established, telecommuting and flex hours are available to those who so choose. The department is continuously proactive towards new communication technologies to achieve maximum flexibility.

Thank You to our Host

The PhilaSUG Executive Committee wishes to thank Karen K. Curran, Senior Director of Global Programming, Biometrics, Theorem Clinical Research. In addition, we wish to thank Jessica Lam and John Cohen of the PhilaSUG Executive Committee for their efforts to coordinate this meeting.

Host Sites Wanted

We continuously seek host sites for future PhilaSUG meetings. There is not a lot of work involved, and it is a great way to put your company on the local SAS map. We need your help with this. If your company would like to host a meeting, within reasonable geographic proximity to Philadelphia, PhilaSUG would be grateful if you would contact Randy Noga at President@PhilaSUG.org.

E-mail Announcements

PhilaSUG-L is a low volume, announcement-only e-mail notification service provided free of charge to all members who wish to subscribe. In order to sign up for this service, you need only send a blank e-mail message to: PhilaSUG-L-subscribe@onelist.com. Note that you can subscribe as many times with as many different e-mail addresses as you wish to have the e-mail sent to; e.g., home and office.

PhilaSUG Web Site

Our site on the World Wide Web always contains the latest information concerning upcoming meetings, SAS training and seminars, links to SAS related hot topics, and local SAS job opportunities.



Visit us regularly at: <http://www.PhilaSUG.org>

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Kajal Tahiliani

Presenters Wanted



You are invited to be a Presenter - PhilaSUG constantly seeks individuals who wish to participate actively in our meetings by presenting various SAS topics in the form of delivered papers or posters. This is a great way to share your knowledge with others, to brush up your presentation prior to delivery at NESUG or SGF or some other major conference, and to gain confidence as a speaker. Short technical SAS related articles are also desired for inclusion in the Newsletter. If this is of interest to you, please use the online abstract submission form found on our web site. Presentations can be from a few minutes to 50 minutes. If you wish to participate, the deadline for the winter meeting is **January 8, 2012**. Your abstract must be submitted online at our web site.

Future Meetings and Events



Next PhilaSUG Meeting

PhilaSUG Winter 2012 Meeting

Date: TBA, we're planning week of 3/5

Hosted by The Wharton School of the University of Pennsylvania

Watch our Web Site for details as they develop



NESUG 2012

November 11-14, 2012

Renaissance Hotel
Baltimore, Maryland

Paper Abstracts

Caution: Hazards Crossing! Using the Renyi Test Statistic in Survival Analysis

Matthew Davis, M.S., Theorem Clinical Research
Sharon X. Xie, Ph.D., University of Pennsylvania

One of the main assumptions regarding a number of survival analysis techniques is that of proportional hazards. If the hazard rates are found to cross, analyses such as Cox proportional hazards regression and log-rank test will either lose power or be rendered inadequate. One way to adequately analyze survival data with crossing hazard rates is to obtain inference using the Renyi test statistic. Both an example and a macro will be provided to calculate the Renyi test statistic with various weights.

Survival analysis is a breakthrough in analyzing statistics that has become invaluable to the analysis of pharmaceutical data. It uses all available information of the time to event data by appropriately incorporating censoring information. It benefits greatly from the Martingale counting process instead of any specific distribution. For comparison of survival curves among groups, weighted or unweighted log-rank tests are often used. These tests were based on the weighted integral of estimated difference between the cumulative hazard rates. For two sample tests, the

log-rank test has optimal local power to detect differences in the hazard rates, when the hazard rates are proportional (Klein 2003). However, when the hazard rates cross, these tests have little power. Similarly, Cox proportional hazard models require the hazards are proportional.

This presentation focuses primarily on survival analysis techniques on group comparisons when the hazard rates cross (non-proportional hazards). When we find evidence of non-proportional hazards, the analysis of the data using classical log-rank or Cox Proportional Hazards can become more difficult. While there are certainly ways to analyze the data in spite of this weakness, particularly for Cox Proportional Hazards models, it would be helpful to have a resource that allows us to analyze the data in the most parsimonious manner. In that light, the Renyi family of test statistics can be computed which, similar to the Log-Rank or Wilcoxon tests in Kaplan Meier analysis, will help determine if there is a significant difference in survival rate between two groups given the presence of crossing hazard rates. To this point, SAS® has not incorporated the Renyi family of statistics into their PROC LIFETEST procedures. Therefore, after a brief history of the Renyi family of statistics and some of the math behind these analyses, an example will be given where the Renyi statistic is appropriate along with the SAS code needed to perform the analysis.

Mat has worked at Theorem Clinical Research for three years. He has presented at PharmaSUG for the last 3 years and won runner-up for best statistics paper in 2011. He is a second year PhD student at UPENN.

A Regular Language: The Annotated Case Report Form
Ryan Wilkins, PPD, Inc.

As per CDISC and FDA regulatory requirements, including a link to the Annotated CRF (aCRF) from the metadata definitions facilitates a clear and transparent review of the clinical data supporting a regulatory submission. In practice, providing this link can lead to a costly development of the electronic Case Report Tabulations (eCRT) or define.xml. This presentation describes an automated approach rooted on the basis of Backus-Naur Form (BNF) to define the standard CDISC annotation construct. Then, using an

intuitive design and a combination of tools – Adobe Acrobat, SAS XML Mapper, SAS Perl Regular Expression functions, and data step logic – programmatically applies and validates the links found in the define.xml at a drastically lower cost.

Ryan Wilkins, M.S. is a Senior Programmer Analyst in PPD's Biostatistics Wilmington, NC office. Mr. Wilkins has a total of four years of experience in clinical trials with more than two years of experience as lead programmer on clinical trials in heart, lung, liver and kidney transplants, more than one year experience as a lead programmer on trials in diseases of the respiratory system, and more than three years experience as a support programmer in trials in a variety of therapeutic areas. Mr. Wilkins received his M.S. in Computer Science and Information Systems from the University of North Carolina at Wilmington in 2007. Mr. Wilkins has more than eight years of experience working with several programming languages and four years of industry experience in SAS programming, with a particular focus in CDISC standards.

From Stocks to Flows: Using Hash objects for FIFO, LIFO, and other FO's
Mark Keintz, University of Pennsylvania

Tracking gains or losses from the purchase and sale of diverse equity holdings depends in part on whether stocks sold are assumed to be from earliest lots acquired (a FIFO list) or the latest lots acquired (LIFO). Other inventory tracking applications have a similar need for application of either FIFO or LIFO rules. This presentation shows how a collection of simple ordered hash objects, in combination with a hash-of-hashes is a made-to-order technique for easy data-step implementation of FIFO, LIFO, and other less-likely rules (e.g. HIFO and LOFO).

Mark is a Senior Data Analyst at Wharton Research Data Services. His interests are primarily in development of financial research and education applications and efficient use of large data sets..



Introduction to ODS Graphics for the Non-Statistician

Mark Mike Kalt and Cynthia Zender,
SAS Institute Inc., Cary, NC

Are you a History, English, or other humanities major who has stumbled into SAS® programming? Are you a business analyst or report analyst whose statistical knowledge ends with mean, median, percentiles, and standard deviation? Don't know a fitted loess curve from a survival estimate? Need to produce some series plots and bar charts and maybe the occasional box plot? Don't panic! This presentation is for you!

This presentation illustrates how to use Base® SAS procedures and new statistical graphics (SG) procedures (in particular, SGPLOT and SGPANEL) in SAS/GRAPH to produce simple plots and bar charts. Once you know the basics of the SGPLOT statements to produce single graphs, learning SGPANEL to create paneled output will be a cinch. Through concrete examples, this paper will guide you through the basics of producing and customizing simple graphs using the new SG procedures. In addition, use of the ODS GRAPHICS statement for setting graph options is covered. (Note: The SGRENDER procedure falls outside the scope of this presentation.)

Although ODS Graphics was initially designed to make the production of standard statistical graphics easier, its capabilities are also well suited for the production of non-statistical, or business graphics. This presentation is an introduction to the general capabilities of ODS Graphics. It is not intended to provide complete syntax information, but rather to illustrate general approaches to creating commonly used business graphics.



Cynthia Zender has been with SAS since 1996 as an instructor and course developer. She currently serves as the Curriculum Manager for the Report Writing and Output Delivery System curriculum. Cynthia is a SAS Certified Professional, with over 25 years of experience programming and reporting with SAS. Prior to joining SAS, she worked with a variety of industries (including education, public utilities, and telecom), using SAS for application development and report writing. She has recently co-authored a book, "Output Delivery System: The Basics and Beyond" with Lauren Haworth and Michele Burlen.

What Does Metadata-Driven Processing Actually Mean?

Barry R. Cohen, Octagon Research Solutions

Many clinical trials organizations have set a goal to conduct a standards-based and metadata-driven clinical data lifecycle. Most people understand the meaning of a standards-based lifecycle, but many might find it difficult to explain the meaning of metadata-driven processing. I will describe how metadata-driven processing is tightly woven to standards-based processing, and is the way in which an organization can maximize the value it gets from its effort to develop and use CDISC standards-based data definitions. I will describe components of a metadata-driven process at various points in the clinical data lifecycle including, for example: during trial design, during study build in the EDC environment, during ETL from a collection system to a clinical data repository, and during table generation in a statistical computing environment.

The primary goal of this presentation is to help people clarify their vision for how they will maximize the value of using CDISC standards, specifically through the use of metadata-driven processing.

Barry Cohen leads the clinical process consulting group at Octagon Research Solutions. His group engages with clinical trials organizations on the strategic, design, and operational levels to help them best integrate CDISC standards into their clinical data lifecycle.



Poster Abstracts

SAS® Options to Insert a Zero Row *Kajal Tahiliani, ICON Clinical Research*

Programmers often need to summarize data into tables as per the mockup. But our study data might not necessarily have all the data combinations as required in the table mockup. In such cases we need to add zero rows for data combinations that do not exist in the study data and insert them into our results. In my paper I discuss several different methods to add a zero row and a few SAS options that make this process simpler.

Kajal Tahiliani works as SAS Programmer, Analyst II at ICON Clinical Research. With over 6 years of experience in the Pharmaceutical Industry she is highly experienced in programming for Phase I, II, III, post marketing analysis, ISS, ISE, IND and BLA submissions and well versed with SDTM and ADAM standards.. Kajal is Base & Advance SAS certified and holds a MS Degree in Biomedical Engineering from University of Texas at Arlington and is also pursuing a MS in Applied Statistics from West Chester University. Prior to her position at ICON, she has also worked at Merck and J&J.



Execute Your SAS® Code With a Button *Linshan Yuan, Octagon Research Solutions*

The SAS system allows users to develop customized buttons in the toolbar. With this feature, you can assign the functions of your useful codes or macros to buttons. This poster will show how we successfully made our log checking macro into a button that programmers can invoke with just a click. This macro checks the log and produces a summary in the output window.

Linshan Yuan is presently working as a clinical SAS programmer at Octagon Research Solutions Inc. She is an experienced SAS user with both Advanced and Base SAS certificates and graduated with M.S. Degree in Biostatistics from Georgetown University.



Philadelphia Area SAS User Group (**PhilaSUG**) Membership Form

To speed through registration complete this form (please print) and return it to the registration desk of any PhilaSUG meeting (do **NOT** mail it). Checks should be made payable to PhilaSUG. Our membership year runs from Jan. 1 to Dec. 31. Dues for the year are \$30.

This is a ___ new, ___ renewal or ___ update / correction.

Name: _____

Affiliation: _____

Address: _____

City: _____ STATE: _____ Zip: _____

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Check this box (Opt In) if you agree to allow us to share ***your name, address and email address with SAS.***

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(Be sure to clearly distinguish a dash, period and underscore)

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