Bay Area SAS® Users Group

BASAS Newsletter November 2017

Newsletter for SAS® Programmers in the San Francisco Bay Area

Bay Area SAS® Meeting Announcement

Dear BASAS User Group Member,

The next meeting of the Bay Area SAS Users Group will be held on **November 17th, 2017**. Your Bay Area SAS peers, colleagues and friends will come together to exchange ideas, job/contract opportunities, and for networking.

We have four featured speakers, roundtable discussion, and open time where you can share concepts, ideas and a great networking opportunities.

Please bring along your business cards, not only for networking, but to facilitate our registration process.

There will be a bulletin board where job and/or contract opportunities, related events, and other announcements can be affixed. Hiring managers and consultants seeking contracts should bring their requirements on hardcopy for distribution as well as to post on the board.

RSVP Method:

Pleas click **R.S.V.P** and fill in your information. Your timely reply will help us in ensuring adequate seating and refreshments.

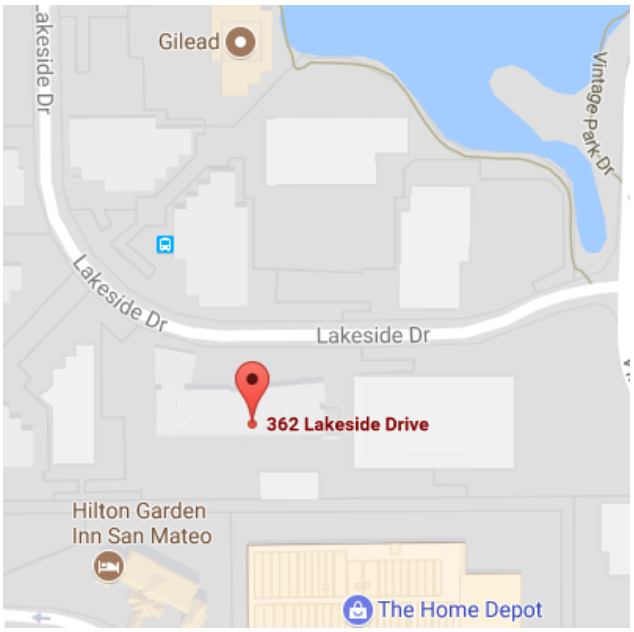
Details of the Meeting

Date:	Friday, November 17th, 2017
Time:	12:00 PM (Registration) 12:30 PM – 4:30 PM (Meeting)
Location:	Gilead Sciences 362 Lakeside Drive Foster City, CA 94404 Building 362 Lecture Hall

Meeting Contacts

Facility Host:	Amy Caron amy.caron@gilead.com
Event Host:	Thomas Leung (415) 956-3611 tleung@tmcsoftware.com

Map of Gilead Sciences.



DIRECTIONS FROM SOUTH BAY:

- Take exit 9B to merge onto US-101 N toward SF.
- Exit at 414B to merge onto CA-92E toward San Mateo Bridge / Hayward.
- Use right lane to take Exit 14B toward Foster City Blvd / East Hillsdale Blvd.
- Use right 2 lanes to turn right onto Metro Center Blvd.
- Turn right onto Vintage Park Dr, then left at the 3rd cross street onto Lakeside Drive.
- Destination will be on the left.

DIRECTIONS FROM EAST BAY:

- Merge onto I-880 S.
- Take Exit 27 A to merge onto CA-92 W toward San Mateo Bridge / Jackson St.
- Take Exit 14B for Foster City Blvd / East Hillsdale Blvd.
- Keep left at the fork to continue toward Chess Dr.
- Take Vintage Park Dr. to Lakeside Dr.
- Turn left onto Chess Dr. and turn right at the 2nd cross street onto Vintage Park Dr.
- Turn left onto Lakeside Dr.
- Destination will be on the left.

Bay Area SAS® Meeting Agenda

"SDTMs in Medical Devices - A First Attempt"
Phil Hall, Edward Lifesciences

"A Critique of Implementing the Submission Data Tabulation Model (SDTM) for Drugs and Medical Devices"
Carey Smoak, DataCeutics

"Which Paint Brush Shall I Choose?"
Helen Shi, Santen Inc.

"Practical tips when using ODS and SG procedures to generate clinical trial graphs"
Yi-ting Lin, Gilead Sciences

More about the meeting:

"SDTMs in Medical Devices - A First Attempt"
Phil Hall, Edward Lifesciences

Abstract:

While clinical trial data of pharmaceutical and medical devices have a lot in common, the differences can be difficult to deal with in SDTMs.

This presentation acknowledges the similarities, highlights the differences and serves as a case-study of how the Transcatheter Heart Valve (THV) Statistical Programming group of Edwards Lifesciences has decided to map their raw data into Study Data Tabulation Model (SDTM) domains. This is not intended to be the definitive guide of how to map medical device trial data to SDTM standards but to serve as the opening statement of a conversation.

About the speaker:

Phil Hall is a Distinguished Statistical Programmer at Edwards Lifesciences, a global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring, head-quartered in Irvine, California.

He has a Bachelor's Degree in Applied Statistics and a Master's Degree in Biometry, both from the University of Reading, UK. Before joining Edwards in 2010, Phil had spent his career working in Europe and the US at pharmaceutical companies and CROs as a statistician and statistical programmer.

"A Critique of Implementing the Submission Data Tabulation Model (SDTM) for Drugs and Medical Devices"
Carey Smoak, DataCeutics

Abstract:

Most SAS programmers in Pharma / Biotech are familiar with the SDTM model. But there are areas of SDTM that are not being fully utilized. These areas include Therapeutic Area User Guides (TAUGs), Associated Persons Implementation Guide (SDTMIG-AP) and SDTM for Medical Devices (SDMTIG-MD). This presentation will explain the benefit of fully implementing all of the SDTM standards for Drugs and Medical Devices.

About the speaker:

Carey has been using SAS for 35 years. He is the co-founder and co-leader of the CDISC Medical Device team. He currently works for DataCeutics as a Senior Consultant. He is a frequent speaker at conferences and has more than 40 publications to his credit.

"Which Paint Brush Shall I Choose?"
Helen Shi, Santen Inc.

Abstract:

I will mainly talk about the visualization needs involving multiple functions including medical affairs, pharmacovigilance, regulatory, publishing, data management and clinical operations during clinical trial. By breaking down their needs by analysis level, timeliness and display format, we will map SAS and other software tools according to these needs from our setting and how as programmers we can manage the painter box for these requests.

About the speaker:

Helen Shi has been in clinical data programming for 5 years at Santen Inc. Being a Subject Matter Expert for SAS Life Science Analysis Framework and visualization, Helen is passionate about supporting good decision making along pipeline and moving innovations from bench to market in various countries.

Helen has also got the Stanford Advanced Project Management certificate in 2015. She serves on the board of a youth entrepreneurship organization. She enjoys playing the violin and board games in her pastime.

"Practical tips when using ODS and SG procedures to generate clinical trial graphs"
Yi-ting Lin, Gilead Sciences

Abstract:

Graphic reporting is important for clinical trial not only graphs are part of CSR TFLs but also in exploratory analysis toward publication or research purpose. SAS ODS and SG (Statistical Graphics) procedures are developed to easily facilitate the needs for different types of graphs.

But several hours can be spent to find the solution for some fundamental graph area issues such as modifying the size or location of graph area vs plot area, or where to turn off/on graph border or plot border. Since there are so many details about SAS graph programming, it is good to know some practical tips that can save your day when using ODS and SG procedures for clinical trial graphs.

About the Speaker:

Yi-ting Lin has been working in biotech/pharmaceutical industry for over 13 years as a statistical analyst and statistical programmer. She is with Gilead Science for 6 years and currently works as a Sr. Manager of Statistical Programming in Liver Disease Therapeutic Area. She supported multiple HCV NDA for FDA submission and now leads a team to support multiple liver fibrosis projects.

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