PaperNumbner	Title	Authors	Abstract	Section	Affiliation	Country
PT01	Essentials of PDV: Directing the Aim to Understanding the DATA Step!	Arthur Li	Beginning programmers often tend to focus on learning syntax without understanding how SAS® processes data during the compilation and execution phases. SAS creates a new data set, one observation at a time, from the program data vector (PDV). Understanding how and why each of the automatic or user-defined variables is initialized and retained in the PDV is essential for writing an accurate program. Among these variables, the following variables deserve special attention, including variables that are created in the DATA step, by using the RETAIN or the SUM statement, and via by-group processing (FIRST.VARIABLE and LAST.VARIABLE). In this paper, you will be exposed to what happens in the PDV and how these variables are retained from various applications.	Programming Techniques (PT)	City of Hope Medical Center	United States
PT04	Quick Graphs with ODS Graphics Designer	Sanjay Matange	You just got the results of the study and you want to get some quick graphical views of the data before you begin the analysis. Do you need a crash course in the SG procedures just to get a simple histogram? What to do? The ODS Graphics Designer is the answer. With this application you can create many graphs including histograms, scatter plots, scatter plot matrices, classification panels and more using an interactive 'drag-and-drop' process. You can render your graph in batch with new data and output the results to any open destination. You can view the generated GTL code as a leg up to GTL programming. You can do all this without cracking the book or breaking a sweat.	Programming Techniques (PT)	SAS	United States
CC01	Annotate your SGPLOT Graphs	Sanjay Matange	The SG procedures provide you multiple plot statements to create many different kind of graphs. These plot statements can be used together in creative ways to build your graph. However, even with this ability to customize, there are times when you need more than what you can get using just the plot statements. You need a way to add custom information anywhere on the graph. With SAS 9.3, the SG procedures support the ability to annotate the graph using data set based information. This annotation functionality is designed in a way similar to the annotate facility available with the SAS/GRAPH procedures. There are a few differences and enhancements. If you already know annotation from SAS/GRAPH, or if you are new to it, this paper will show you how to add custom annotations to your graphs.	Programming Techniques (PT)	SAS	United States

CD01	Creating Define.xml v2 Using SAS for FDA Submission	Qinghua Chen	When submitting clinical data to the Food and Drug Administration (FDA), besides the usual trials results, we need to submit the information that helps the FDA to understand the data. The FDA has required the CDISC Case Report Tabulation Data Definition Specification (Define-XML) based on the CDISC Operational Data Model ODM) for submissions using Study Data Tabulation Model (SDTM). Electronic Submission to the FDA is therefore a process of following the guidelines from CDISC and FDA. This paper will illustrate how to create an FDA guidance compliant define.xml v2 from metadata using SAS.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)		United States
PT05	Napoleon Plot	Kriss Harris	Do you want to produce a very useful plot? Okay, do you want to produce a plot that for each subject shows the number of treatment cycles, the number of days on treatment, the doses that were received, whether the subject has discontinued treatment, and the cohort the subject is in? This paper will demonstrate how to do the above in SAS® 9.4.	Programming Techniques (PT)	SAS Specialists Ltd	United Kingdom
BACK	Functioning at a Higher Level: Using SAS® Functions to Improve Your Code	Peter Eberhardt and Lucheng Shao	SAS® provides many built in functions that will help you write cleaner, faster code. With each new release of SAS there are new functions added; in many cases these new functions are overlooked because we have developed coding habits to try to accomplish the same result as these functions. In this paper we will survey some functions we find useful. In addition we will touch on how you can turn your code habits into functions.	Application Development (AD)		Canada
DM01	I Object: SAS® Does Objects with DS2	Peter Eberhardt and Xue Yao	The DATA step has served SAS® programmers well over the years, and although it is powerful, it has not fundamentally changed. With DS2, SAS has introduced a ficant alternative to the DATA step by introducing an object-oriented programming environment. In this paper, we share our experiences with getting started with DS2 and learning to use it to access, manage, and share data in a scalable, threaded, and standards-based way.	Data Management & Validation (DM)		Canada

AD01	PROC FCMP: I Cannot Function Without It.	Peter Eberhardt	How many times have you tried to simplify your code with LINK/RETURN statements? How much grief have you put yourself through trying to create macro functions to encapsulate business logic? How many times have you uttered "If only I could call this DATA Step as a function"? If any of these statements describe you, then the new features of PROC FCMP are for you. If none of these statements describe you, then you really need the new features of PROC FCMP. This paper will get you tarted with everything you need to write, test, and distribute your own "data step" functions with the PROC FCMP. This paper is intended for beginner to termediate programmers, although anyone wanting to learn about PROC FCMP can benefit.	Application Development (AD)	Fernwood Consulting Group Inc.	Canada
PO01	Using Monte Carlo Simulation Methodology to Calculate Sample Size or Power by SAS	Amanda Yao	This paper will introduce the simulation methodology, simulation steps, and it will also take 2 studies with continuous endpoint and binary endpoint for example to introduce how to calculate sample size and study power using MC simulation by SAS. Compared with SAS POWER procedure, it is a great supplement for those complicated or non-standard design studies to get more accurate number into clinical study.	Posters (PP)	ICON	China
PO06	Transpose Dataset by Merge Statement	Keshan Xia, Arthur Tabachneck and Matthew Kastin	We can use Merge statement to transpose dataset just like proc means + idgroup did, but more simple and no need to reorder or rename the variables. It is very easy to understand if you are familiar with MERGE statement and SQL a little bit.	Programming Techniques (PT)		China
CD03	Design and Construct Efficacy Analysis Datasets in Later Phase Oncology Study	Huadan Li and Changhong Shi	Under the CDISC frames, The Therapeutic Area Standards (TA Standards) have already been the hotspot. The CFAST TA Standards Program was launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools and methods for nducting research in therapeutic areas important to public health. The Oncology TA is the pioneer of this effort. The SDTM Oncology domain models for umor Identification (TU), Tumor esults (TR) and Disease Response (RS) are ailable in SDTMIG v3.1.3. However, the Oncology TA ADaM has not achieved any standardization. This paper will demonstrate how to design and construct standard efficacy analysis datasets in later phase Oncology studies according o the SDTM Oncology domain models.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	MSD	China

MC02	My Ideas on Clinical SAS Programmer's Training Program	LIXIANG YAO	Abstract: This paper is to introduce the training programs proved to the junior clinical SAS programmer in the first few months. Compared with pure SAS pogrammers in other industries, clinical SAS programmer should know a lot of additional knowledge rather than SAS to be a skilled one. And to provide clinical SAS programmers the trainings logically is quite important to let a junior one become a middle one in a short time. And we will introduce what kills can be provided to clinical SAS programmer and in what way we transfer the knowledge to the clinical programmer. It is assumed that the programmer to take this program has SAS knowledge.	Management & Career Development (MC)	icon	China
CC06	I Am Legend	Kriss Harris	Have you ever produced a legend on a plot that was taking up too much space, hence making the actual graph too small? Have you ever removed a legend because it was taking up too much space? Have you ever wanted to just produce a legend? Have you ever wondered that there must be a more efficient way of producing a legend then using the exact same legend on every BY variable of your output? This paper will demonstrate solutions to the above problems using Graph Template Language (GTL) in SAS® 9.2, in particularly using the SERIES, VECTOR and SCATTERPLOT statements.	Programming Techniques (PT)	SAS Specialists Ltd	United Kingdom
SP01	Continual Reassessment Method (CRM) in Dose-finding Trials	Vicky Pan	Traditionally, a dose-finding trial is based solely on toxicity categorized as binary outcome (i.e., YES or NO), that found wide application in clinical trials including the 3+3 design. However it is neither the most effective nor the most efficient statistical tool that can be utilized in such trials. Continual reassessment method (CRM) is based on a parametric model on ose-toxicity relationship, and uses accumulating data to continuously update the estimate of the dose-toxicity relationship so that we can make the best decision of dose assignment for the next patient. This reflects what clinicians ctually do in practice and has been shown to work well even in trials with relatively small total sample size. This poster provides a high level summary of various CRM techniques including demonstration by simulation.	Statistics, Pharmacokinetics & Health Outcome (SP)	INC Research	China

SP08	Forecast number of events in oncology trials: parametric method and non-parametric method	Yan Qiao	In this paper, we will discuss 2 methods to calculate the number of events at a future timepoint in oncology clinical trials: parametric method and non-parametric hod. Parametric method assumes gamma distribution for event rate and drop-out rate, and the parameter of the distribution can be either based on the assumption from the planning phase, or updated with avaibalbe data when the trial is ongoing. Randon samples are drawn from the gamma distribution. For each subject, a probability of event at time t is calculated. (If an event already occured to this subject, the probability of event is 1; if this subject already dropped out, the probability of event is 0.) The the sum of event probabilities is calsulated for each sample. The median and CI can be calculated across all random samples. Non-parametric method generates bootstrap samples from the original dataset. For each subject without event or drop-out in the bootstrap samples, the subject's event/drop-out time can be drawn from KM distribution based on the data from subjects with longer event/drop-out times. For example, if subject i is in the bootstramp sample and has no event or drop-out. Select all the subjects in the bootstramp sample with longer observed times than the observed time of subject i. Draw KM curve of the event/drop-out time from all the selected subjects. If this KM curve dosen't reach 0, an exponential model needs to be fitted to the tail, to get a complete KM curve. Randomly select event/drop-out time based on the probability in this newly created KM curve and assign them to subject i. Determine the event status for subject i at t based on the randomly assigned event/drop-out time. Repeat this for all the subjects without event or drop-out in this bootstrap sample and for all bootstrap samples. Then the sum of events can be calculated for each bootstrap sample and the median and CI can be calculated across all random samples.	Statistics, Pharmacokinetics & Health Outcome (SP)	MerckSerono	China
CC07	Plotting Against Cancer: Creating Oncology Plots Using SAS®	Debpriya Sarkar	Graphs in oncology studies are essential for getting more insight about the clinical data. This presentation demonstrates how ODS Graphics can be effectively and asily used to create graphs used in oncology studies. We discuss some examples and illustrate how to create plots like drug concentration versus time plots, waterfall charts, comparative survival plots, and other graphs using Graph Template Language and ODS Graphics procedures. These can be easily incorporated into a clinical report.	Programming Techniques (PT)	SAS Research & Development (India) Pvt Ltd	India

BACK	Effectively Utilizing Loops and Arrays in the DATA Step	Arthur Li	The implicit loop refers to the DATA step repetitively reading data and creating observations, one at a time. The explicit loop, which utilizes the iterative DO, DO WHILE, or DO UNTIL statements, is used to repetitively execute certain SAS® statements within each iteration of the DATA step execution. Utilizing explicit loops is ften used to simulate data and to perform a certain computation repetitively. However, when an explicit loop is used along with array processing, the applications are extended widely, which includes transposing data, performing computations across variables, etc. Being able to write a successful program that uses loops and arrays, one needs to know the contents in the program data vector (PDV) during the DATA step execution, which is the fundamental concept of DATA step rogramming. This paper will cover the basic concepts of the PDV, which is often ignored by novice programmers, and then will illustrate how utilizing loops and arrays to transform lengthy code into more efficient programs.	Programming Techniques (PT)	City of Hope Medical Center	United States
PT02	The Power of SAS National Language Support - Embrace Multilingual Data	CHAO WANG	As clinical trials take place around the globe, data in different languages may need to be handled. The usual solution for this issue is to translate the data to English, after some manipulations, results then will be translated back to the original language. Since version 9.1.2, SAS software can provide a specific function called National Language Support, this issue would be easy to handle. In this paper, an introduction will be made on: 1) how to build the ready SAS session to import and display the mixed data with NLS system option 2) how to use the edge tool – SAS K-Function (including K-macro Function) to do data manipulations and 3) how to display any character in reports with the Unicode support. Here would use a multilingual (Chinese and English) AE dataset as an example on SAS 9.3 PC version. The related applications on the UNIX server and SAS enterprise guide would also be discussed.	Programming Techniques (PT)	MSD R&D (China) Ltd.	China
PO07	How to uniform the variable's length	Keshan Xia, Arthur Tabachneck and Matthew Kastin	In the reality, We usually need to use SET statement to union multiple datasets which have the same variables name. But when the variable's length from different dataset is different, we usually are going to get wrong result.This can be solved by SQL easily and fast.	Programming Techniques (PT)		China

AD04	One Click to Generate the PK Analysis Outputs in Clinpharm Study	Zhi Xu, Jianyong Tong, Huadan Li and Xin Deng	ABSTRACT - In order to improve the delivery quality, increase productivity, and empower better decision making in PK studies we initiate a program called “Standard Statistical SAS Macros for the Analysis of Pharmacokinetic Parameters in EDS PK studies”. Through this initiative, we aimed to develop three kinds of tools: 1) Metadata-based centralized macro programs; 2) Programs templates that depend on the study type and use the centralized macros; 3) ADaM templates for generating the ADPP and ADPC. The most important part is centralized macro and it will cover both table and graph. The analysis methods and related output will include 1) any linear fixed/mixed effects model on any log-transformed parameters and its outputs; 2) the standard power model for dose proportionality analysis in a parallel groups (cross-over) design and its outputs 3) the standard non-linear mixed effects model for steady-state analysis in a multiple dose study and its outputs; 4) the standard linear model for steady-state analysis in a multiple dose study and its outputs; 5) computes descriptive statistics on any list of parameter and provides the related summary table; 6)Plot the ratio plot for the ratio of GMR. Key word: Metadata-based centralized macro, PK studies, ADaM	Application Development (AD)	MSD	China

AD05	From Coal Mining to Data Mining: Advancing Programming Management for Clinical Projects with Text Analytics	Zhouming(Victor) Sun	ABSTRACT - Both coal mining and data mining involve the process of extracting valuable materials from raw resources to form economically useful packages. Due to the theoretical similarities behind these two different types of mining, the process of coal mining, as will be described, serves as inspiration for the development of the Simultaneous Monitoring of Analysis and Reporting Toolkit (SMART), a method for data mining based on the techniques of text analytics using Base SAS@ 9+. Established with a general SAS macro, SMART is a versatile toolkit that allows for the reporting of the real-time status of programming activities. By using the techniques of text analytics to find explicit relationships between documents by classifying documents into predefined or data-driven categories, SMART makes management of clinical project programming more effective and dynamic. This paper will introduce the concepts of SMART, followed by a presentation of its four key processes. It will additionally demonstrate the power of text analytics in extracting useful information while providing a helpful roadmap for project leaders to efficiently manage programming activities independently of a project leader's programming skill or experience.	Application Development (AD)	Medimmune	United States
AD06	Scheduling SAS®Jobs When You are Away	Xiaojin Qin	Imaging your SAS jobs can run at a scheduled time and on a repetitive basis like a tinny robot? Yes, this paper will guide you to do that. There are many ways to schedule SAS tasks. This paper will only focus on the built-in "scheduler" function of the SAS Enterprise Guide. This function has the superiority of scheduling project/job without any manual intervention. If you have a SAS reports due every day but you're tired of running the same jobs over and over again, let's move up!	Application Development (AD)	Covance Pharmaceutical R&D Co., Ltd.	China
CD06	Easy ADaM implementation: Case Study	Victor WU	With the popularization of CDISC, more and more interests are shown on how to implement CDISC standards to create CDISC-Conformed datasets. Here I would like to show how to create ADaM datasets step by step. Proposed solutions to most frequently encountered issues will be discussed, such as assigning attributes to dataset/variables, selecting baseline, and deriving new variables vs deriving new records; and several related macros will be introduced to demonstrate how to implement easily.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	PPD	China

CC02	Marco free automation to identify and drop variables with all values as missing	Vamse Goutam and Amarnath Vijayarangan	Missing values do have a vital role to play in handling data either numeric or character. Especially when a variable is completely missing it taxes the execution speed and also the space that the dataset occupies. However, if we are able to identify these missing variables even before the analysis or study and drop them it would significantly increase the execution speed and would also save a good impactful amount of space in the server. There are several solutions to this problem, but this paper introduces a macro free automation to identify and then drop the completely missing variables, as any use of macros or even a simple proc freq would run into a risk of either a complete failure or slowdown of the process due to insufficient macro length or numerous levels in the dataset. Various SAS procedures can be used to identify the variables with completely missing values and then an implementation of a data step or proc step will drop these missing variables. But this is a onetime solution for smaller datasets. In case of a repetitive task or larger datasets it is always efficient to execute it through an automated process. Here we propose an automated solution and to make it even more efficient and simple we do not use any macros in it thus making it completely a macro free automated process to identify and drop the variables with completely missing values	Coder's Corner (CC)	Genpact	India

PO08	SAS2VBA2SAS: Automated solution to string truncation in PROC IMPORT excel	Amarnath Vijayarangan	SAS Proc import is one of the greatest approaches for converting other software's data files into SAS datasets. While importing the files string truncation of a character variable is a common pitfall to every SAS users. Most of the times, values of a character variables are having dissimilar length such as product names, descriptions & retailer address. In this case, Proc import may not be able to retain the values as it is since it fixes the length attribute using GuessingRows as 20. Alternatively data step with infile statement can be used which requires significant effort even for a smaller file and is error prone. Our proposed approach is making use of SAS & VBA to resolve the length issue of a character variable. Fortunately, Proc import generates the data step program in the log. VBA reads the log for character variables and then reads in excel file to get maximum length for each variable from excel by scanning length of each values for every variable. The data step program will be modified with this maximum length for the character variables using VBA. This new modified data step program then will be executed to import the excel file without any truncation of character variable. This approach also does the importing of several files at a time.	Coder's Corner (CC)	Genpact	India
PT06	Hash table and its use in the big data analysis of healthcare claims database	Weston Chen	With the increasing needs on the analysis of big data-enormous amounts of information collected in the healthcare information system, how to develop more efficient codes has become one of the key skills SAS users have to master. SAS itself provides multiple ways for efficiency considerations. Hash table is one of them. This paper will show you how to create a hash object in data steps and some useful techniques to address big data match-merge and/or join operations. In addition, some performance comparisons will be made between typical data lookup techniques and hash table with the use of real-world big healthcare data to show the impressive efficiency improvement by hash object. Some additional practical tips about creating Hash objects for efficient programming would be introduced as well.	Programming Techniques (PT)	Novartis	China

MC03	A SAS Programmer's Dream	Yong Zhao	With the introduction of the latest Chinese government, a concept of China dream has been given a lot of publicity. It may sound very vague and remote, but I am sure every SAS programmer has his/her own dream in career development. Being a SAS programmer is a unique experience we all enjoy. We have our own culture and characteristics because we're both programmers and analysts. We also work in a very special pharmaceutical environment which has a lot of regulations and requires a great deal of quality work. In order to be able to climb in this kind of corporate ladder, it requires a lot of efforts from each individual. The focus of the presentation is to have a positive discussion on how to fulfill our dreams. It will include topics such as how to set up your goals, how to improve your technical and communication skills and how to get ready for your next position. I am going to use psychological theories and my personal experience as manager with a large group of direct reports to launch an open discussion on the topic we all care deeply about, how to fullfill our dreams. I'd propose some suggestions on areas we may be able to improve and to invite people to share their ideas.	Management & Career Development (MC)	inVentiv	United States
SP05	Exposure-adjusted Incidence Rate Analysis of Subjects with Specific Adverse Events in Clinical Trial	Peng Wan and Xuebo Pi	Normally the standard summary analysis of adverse events (AE) in clinical trial is defined as the percentage of subjects with a specific adverse event in each reatment group. This might not be appropriate as it does not account for individual subject's l exposure time. Sometimes adverse event can be also analyzed using another refined statistical method called the exposure-adjusted incidence rate, which is defined as the number of subjects experienced adverse event divided by the total exposure-time among subjects in each treatment group. This paper will illustrate the way to generate the analysis dataset for adverse event and calculate adjusted incidence rates and confidence intervals using SAS code.	Statistics, Pharmacokinetics & Health Outcome (SP)	MSD	China
PO02	A simple way to access the data in EXCEL through SAS v9/ ACCESS® libname and Excel engine	Lianbo Zhang	Aiming to summarize libname access and Excel engines which is useful to read excel file into SAS dataset but not familiar to many people who prefer to PROC IMPORT' or 'infile input'. This paper will discuss the principle and useful techniques about data transform between SAS and Excel, including named range, spreadsheet, libname, Excel engines. And also solving some problems we may meet. We use SAS® 9.3 64-bit and Excel 2013 64-bit in win7 x64. SAS/ACCESS® software for PC files must be available when we use the Excel engine.	Coder's Corner (CC)	Fountain Medical Development	China

CD09	How to meet one new FDA requirement - OSI (Office of Scientific Investigation)	Xuebo Pi and Changhong Shi	Previously known as Division of Scientific Investigation (DSI), the Office of Scientific Investigation (OSI) is now the new FDA requirement for the NDAs consisted of the completed Phase II and Phase III clinical trials. It is administrated under the Office of Compliance, in the Center for Drug Evaluation and Research (CDER). The OSI verifies the integrity of efficacy and safety data and assures that the rights and welfare of clinical participants are protected by conducting risk based site nspections, and also facilitates the FDA's decision on the timely selection of the appropriate sites. Currently, the OSI request only affects submissions to CDER with respect to clinical data. In this paper, the 3-part components of OSI will be introduced and an implementation example will be discussed per a Merck project.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	MSD	China
PO09	Moving Smoothly Between SAS and Excel Using PROC IMPORT	Minfu He, Yuqin (Alice) Liao and Yuan Zhuang	ABSTRACT: PROC IMPORT is one of the most commonly utilized methods of transferring data from Microsoft Excel® to SAS®. Both SAS and Excel are well developed and frequently upgraded. This brings to users the most efficient and exact measures of manipulating data, however this also makes different versions of software and data file co-exist and may cause unexpected errors when using SAS PROC IMPORT to read data from an Excel file if we don't pay enough attention. This paper, focusing on SAS 9 and later, summarizes aspects which should be considered to assure the success of running PROC IMPORT such as Excel engine and version, explains the error that we will encounter, and also gives possible solutions for those kinds of issues. Key Word: IMPORT, Excel	Programming Techniques (PT)	MSD R&D (China) Co., Ltd.	China

PT03	SAS XML Mapper: A bridge connecting PDF Comments, MS excel files, and SAS datasets	Gaoyamg LI	For almost every Clinical SAS programmers, Adobe PDF documents, MS excel files and SAS dataset are the top 3 documents types when conducting data analysis. First, we need review CRF or aCRF, which typically is of PDF documents. Sometimes, they are of RTF or WORD documents. Then, several working documents would be created in MS excel documents, such as domain summary, programming specifications, and external data not from database. And Third step also the most import step is analysis data in SAS datasets. These 3 types' documents are interactive documents, and usually most people deal with them separately or manually. SAS XML Mapper provides a bridge to connect them even if they are not using a standard XML formats. This make a automatic or programmed way happen when. In this paper, XML file, PDF comments as XML Forms Data Formatted (XFDF) file, SAS XML Mapper are esplained. A real example was presented on how to import and parse annotations contained in a blank aCRF to create domain summary and fields details by SAS program with the help of XML Mapper. This example would inspire readers to create other documents in the same way.	Programming Techniques (PT)	Bayer Healthcare	China
PT07	Monitoring Child Growth and Safety Profile using Growth Charts	Rajesh Babu Moorakonda and Mihir Gandhi	In child nutritional trials, graphical presentation of subject-level anthropometric parameters over time is useful to visualize child growth trajectory according to age. The trajectories of selected anthropometric parameters are usually evaluated with reference to a growth chart developed using growth standards, such as World Health Organization (WHO) child growth standards. Growth charts provide expected percentile values of the anthropometric parameters based on children of same gender and age-group from the general population. It is usually important in child nutritional trials to monitor the child growth for potential effect of study product feeding, adverse events and concomitant medications. This paper describes step-by-step procedure for plotting subject-level trajectory of an anthropometric rameter during the trial period on the growth chart developed using WHO child growth standards. the chart also displays details of onset of adverse events as well as intake of concomitant medications. It uses PROC GPLOT and SAS Annotate facilities.	Programming Techniques (PT)	Singapore Clinical Research Institute	Singapore

CC08	Automated Log Analyzer Dashboard	Palanisamy Mohan and Amarnath Vijayarangan	The importance of validating a SAS program through the generated log file is inevitable. A successful execution would require an ERROR, WARNING and other system message free log. Though, the severity of NOTE or WARNING might not be very high, but there are chances for multiple NOTES or WARNINGS together in a program can cause severe problems or incorrect results equal to an error message. The SAS products in various domains generate very large and N number of log files when executed. For instance, Clinical Research domain demands 100 + SAS programs to be either executed in a batch mode or interactive mode for a final delivery, which is validated manually. This means a programmer needs to review 1000 + lines of code in the multiple logs manually where certain seemingly unimportant messages might be overlooked and also a manual review is really time consuming process. The proposed automated log analyzer will help in a 360 degree review of the generated SAS Logs; a program is developed to ensure that no system generated message is overlooked. The automated log analyzer scans each and every single line of every log file in the directory for any system generated messages and provides a visual report: a dashboard using SAS. The dashboard provides an overall summary on various system generated messages by SAS logs or across SAS logs through quality charts which will allow the programmer to quicken the validation process. The dashboard generates three reports 1) System messages captured from each log 2) Frequency messages 3) a visual presentation. This ensures not only accuracy in the validation process but also a significant reduction in the time taken to validate the programs.	Coder's Corner (CC)	Cognizant	India

PO10	To Open SAS Datasets in SAS System Viewer while Compiling the Coding in Enhanced Editor	Weiquan Xin	Oftentimes, SAS programmers open the newly created SAS datasets for a check purpose while they are writing codes in SAS enhanced editor. To do this, they activate the SAS explorer, open the SAS library, locate the SAS dataset, and double click the dataset to open it. Then, VIEWTABLE is used to open the dataset by default. These steps are rather time-consuming and VIEWTABLE is not so user-friendly. Therefore, in the article, we discuss two alternative methods. One convenient method is presented to relieve this issue. While compiling the coding in the enhanced editor, you only need to select the dataset name, and press two shortcut keys, and then the dataset will be opened in SAS system viewer. The other one, to open SAS dataset in the SAS system viewer from SAS explorer, is also briefly discussed.	Coder's Corner (CC)		China
PT08	Introduction and Application of SAS Interactive Matrix Language in Clinical Trial	Yankui Ou	Interactive Matrix Language (IML) in SAS system is very helpful for programming statistical procedures that SAS doesn't have and constructing graphics which could not be created with SAS/GRAPH. If we consider rows and columns of dataset as vectors or matrices, programming work could be easier in some cases. Because IML programming requires expertise of matrix algebra, it is not popular in clinical trial SAS programming. This paper aims to introduce the basic theory of IML procedure and provide some examples of application in clinical trial SAS programming. The following contents will be discussed: 1) Calculating special statistics in statistical model, and 2) Creating graphics using a powerful set of graphics commands in SAS/IML.	Programming Techniques (PT)	PPD	China
SP11	Calculation of Relative Risk and Odds Ratio Using StatXact PROCs	Halimu Haridona	In clinical trials, statistical inference using asymptotic and approximate statistical methods is not applicable for rare events, e.g., calculating the relative risk/odds ratio for low incidence binomial endpoints. This paper introduces how to calculate the relative risk and odds ratio using StatXact PROCs, which is a more reliable method. StatXact PROCs is a statistical package for Exact Nonparametric Inference, developed for SAS users. It can be used to make reliable inferences by exact and Monte Carlo methods when the data are sparse, heavily tied, skewed, or the accuracy of the corresponding large sample theory is in doubt.	Statistics, Pharmacokinetics & Health Outcome (SP)	PPD	China

PO03	A Programmer's Introduction to Reverse Cumulative Distribution Plot in Vaccine Study	Weibin Cai and Huadan Li	The reverse cumulative distribution (RCD) plot becomes an indispensable graph for clinical and statistical review in vaccine clinical trials. Not only can it provide a rapid assessment of important details of distribution for immunogenetic data, but also make the comparison of distributions relatively easier. Although RCD plots are useful, the latest SAS version doesn't provide a standalone procedure to develop them directly. This paper presents a macro and a graph template method that allow programmer to develop RCD plots easily using PROC GPLOT.	Coder's Corner (CC)	MSD	China
CD02	Brief Introduction of Oncology Domains in SDTMIG,Version 3.2	Haishan Kadeerbai	The final document of CDISC Study Data Tabulation Model Implementation Guide (SDTMIG) v3.2 was released in the end of 2013. All of previous annotations in SDTMIG 3.1.3, originally published in 2012, have been incorporated in SDTMIG v3.2 that includes many enhancements and improvements from earlier versions. This paper presents a brief introduction on the newly added oncology domains (TU, TR and RS) in Findings Observation Class, which are extremely useful in oncology clinical trials, mainly focused on: 1) the purpose and usage of the domains; 2) relationship among the domains; 3) the domains' cross-data (domains) linkability /traceability and relationship with other SDTM domains, such as DD (newly added), DM, SC, and with some ADaM datasets like ADTTE, etc.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	PPD Inc.	China
PO04	Collapsing Adverse Event Records	Haiqiang Luo	In clinical trials, the way of collecting adverse events (AEs) is diverse and collapsing AEs sometimes becomes necessary. Categorizing AEs into collapsible and non-collapsible, and collapsing the collapsible AEs are challenging tasks for SAS programmers in the clinical trials. This paper will introduce how to categorize AEs into collapsible and non-collapsible. Three types of collapsible AEs will be discussed. 1) Multiple AEs with same onset date; 2) Multiple AEs with a time contiguous sequence; 3) Overlapping AEs. This paper will introduce the implementation of collapsing and sample SAS codes for each type of collapsible AE records.	Programming Techniques (PT)	PPD	China

CC10	Using SAS SG Procedures to Create and Enhance Figures in Pharmaceutical Industry	Huashan Huo and Shuo Chi	SAS/GRAPH statistical graphics (SG) procedures provide a simple syntax for creating graphics commonly used in exploratory data analysis and for creating customized statistical displays. This paper will focus on 1) how to use SAS SG Procedures to create pharmaceutical figures, 2) Introduce the advantages and enhancements of SAS SG Procedures, 3) New features in SAS SG 9.3 version to enhance both graphic visualization and printer-friendly result, 4) How to prepare statistics for better and flexible graphic visualization using SAS SG.	Programming Techniques (PT)	PPD	China
MC05	Make Innovative Progress: Let's Establish Our Own Standard Statistical SAS Macros	Jianyong Tong	The common model between the programming team of Global Pharmaceutical Company and their regional division is that the global standard macro team provides the standard macro and we use the macro. In order to make our own contribution to the company, to change the passive working model of the AP programming team and improve the efficiency of our work on PK studies in EDS (Early Development Statistics), we decided to initiate a project named "Standard Statistical SAS Macros for the Analysis of Pharmacokinetic Parameters in EDS PK studies", the team members of which include IT, EDS statistics and programmer. To make this project run smoothly, we took several necessary actions, such as specific task allocation, information and resource sharing, biweekly project meeting, consultation to the Global (programming wise and statistical wise), set up accurate and reasonable timeline, etc.. Up until now, we have accomplished ADaM templates for generating the ADPP and ADPC and 6 Metadata-based centralized macro programs and more will come in the future. Through this project we learned that it's important to have the spirit of innovation, it matters when you start to do something and you never know what you are capable of if you don't try.	Management & Career Development (MC)	MSD	China

CC11	Make Sure Your Log Is Clean	Dong Guo and Quan Zhou	SAS log file provides lots of information about the execution of SAS programs. In clinical trial practice, it is usually unacceptable to leave error, warning, or certain special notes in the log. Programmers spend lots of time investigate the log file and fix the issues they might find. However, the messages in SAS log are not always straightforward for programmers to understand and fix. This paper would like to summarize the common issues in SAS log we face in our daily work, and propose solutions on how to fix them. The summary and solutions will be presented in the following order: issues that might be generated from SAS DATA steps; from SAS macros; and then from some SAS procedures. Examples will be provided.	Programming Techniques (PT)	Eli-lilly and Company	China
PO11	Follow Me, Then You'll Never Be Freshman Again!	Yuqin (Alice) Liao and Huadan Li	Abstract - For a new SAS programmer in pharmaceutical industry, how to train himself or herself to gain essential knowledge and to be an expert in this field efficiently in a short time? In this paper, I will lead you to catch a big picture of how to improve yourself to get rid from being a freshman in clinical trial and related SAS skills by sharing with my two years experiences, useful guidance and resources. Follow me and I'll help you to figure out a clear and effective clue about how to move forward to next level from a freshman stage. Key Words: Pharmaceutical industry, Clinical trial, SAS	Management & Career Development (MC)	MSD	China
AD03	Customize your SAS programming toolbar	Xiaofeng Shi	In pharmaceutical companies, statistical programmers should make their SAS programs comply with GPP (Good Programming Practices) and other SOPs regarding statistical programming and validation. This paper briefly introduces how to create a SAS toolbar that facilitates program compliance to GPP and SOPs. Using the toolbar buttons, it's easy to create a program template including a standard program header, main sections of a program and other program codes standardized in each company. And then, this paper will extend to discuss how to customize your own toolbar buttons to make the daily work easier.	Application Development (AD)	Eli Lilly and Company	China

SP03	Compartmental Models in SAS: Application to Model Epidemics	Ka Chun Chong and Chung Ying Zee	Compartment modeling is useful to quantify the spread of elements in a dynamic system. Apart from the Pharmacokinetics-Pharmacodynamics analysis, epidemic modeling is another broad application of compartmental models. In this paper, we demonstrate how to use PROC MODEL and arrays in DATA steps to generate and fit the epidemic models such as the Kermack and McKendrick model and SEIR model. Practical application is demonstrated for the 2009 pandemic A/H1N1.	Statistics, Pharmacokinetics & Health Outcome (SP)	Clinical Trials and Biostatistics Laboratory, Shenzhen Research Institute, The Chinese University of Hong Kong.	China
SP07	Analysis of Multiple Imputation in Conjunction with Robust Regression in Clinical Trials Using SAS	Tongda Che and Peng Wan	In clinical trial, statistician usually design the statistical method based on normal distribution assumption. But sometimes the actual data may turns out departure from normality. If we continue to use the original method, the result would be misleading and inappropriate In this paper, we would introduce the SAS code for an alternate method that could be used to supplement this issue: multiple imputation for handling missing data and repeated sampling, robust regression method for analysis and get the final result using Rubin's formaula .	Statistics, Pharmacokinetics & Health Outcome (SP)		China
CC12	PROGRAMMING FIGURES: BEYOND SGPLOT AND GTL	Kartik Rajan	Setting up programs for figures for CSRs or otherwise comes with its own set of unique challenges, for in addition to accurately presenting data, figures also need to be clean and understandable (more so than tables and listing). This means a programmer often may need to spend a significant amount of time tweaking code and experimenting with the display of a figure in order to get an output that's "just right". This need for customization comes at a cost of increased programming complexity (lots of macro parameters if the figure code is in a macro) or sometimes SAS doesn't directly support what you need to produce. In such cases one needs to go beyond what SGPLOT and GTL offer, for instance by re-building plots using what is on offer, or "tricking" SAS into doing what you need.	Programming Techniques (PT)	Novartis	India

CC05	Creating Dynamic Template using GTL	Faruk Basha Mulla	GTL is a comprehensive language developed for capturing the definition of potentially very complex graphs, unlike traditional graphics. It helps in creating graphs with simple and concise syntax and also provides the means to modify the default Graphical templates provided by SAS for creating sophisticated and/or highly customized graphs. This presentation talks about the dynamic, special dynamic and macro variables. Dynamic variables give the flexibility to produce the similar graphs with different variables without redefining the template. Special dynamic variables are useful to produce the user defined graphs without hardcoding the variable names in GTL. The creation, declaration and use of macro variables in GTL to produce multiple graphs from a single program, and finally how to draw an inset as a table of text, positioning and creating an inset values with the Template. The dynamic template brings in the benefit of reusability that saves the programming time and increases program efficiency.	Coder's Corner (CC)	Novartis	India
CD05	Hoping to do an FDA submission with CDISC compliant? Join me for a Mock Drill !!!	Vijayalakshmi Gajulapalli	In today's modest environment the reduction of the time taken to reach the market is critical to a drug and hence the company's success. The proper approach of its Regulatory Affairs activities is therefore of considerable importance for the company. Inadequate reporting of data or in a form that the regulators can not easily review may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of dollars, pounds or Euros to develop and even a two-month delay in bringing it to the market has considerable financial considerations.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	Novartis	India
CD08	Automating Production of the blankcrf.pdf	Walter Hufford	The annotated blank Case Report Form (blankcrf.pdf) is a critical component of the NDA submission. Per FDA guidance, source data domain, variable name and controlled terminology for each case report form (CRF) item included in the tabulation datasets submitted should be displayed on the blankcrf.pdf. Production of the blankcrf.pdf is a tedious, non-programming task that is increasingly becoming the responsibility of the statistical programmer. This paper describes an easy to use, automated method of annotating the CRF.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	Novartis	United States

SP10	Early Development Stage (EDS) study---A wonderful start for junior SAS programmer	Yuan Zhuang	As junior SAS programmers, given the fact of lacking experiences, a relatively less complicated and direct study design would be a better choice to obtain hands on experiences for projects. Fortunately Early Development Stage (EDS) study provides us such an opportunity to begin with. In this paper, basic knowledge and oncepts of EDS study will be introduced. Meanwhile, commonly used variables (AUC0_last, Cmax, T_half, Tmax), main content in tables and graphs for EDS study (Geometric Mean, Geometric Mean Ratio and Root Mean Square Error) and related calculation methods (Proc Mixed procedure) will be elaborated in detail. Furthermore, some commonly used programming skills for both table and graph generation will be presented as well. Keyword: EDS, Geometric Mean, Geometric Mean Ratio, Proc Mixed	Statistics, Pharmacokinetics & Health Outcome (SP)	MSD R&D (China) Co.Ltd.	China
SP02	Proportions: Stop Worrying and Start Calculating	Hui Wang and Huadan Li	In clinical trial, it is often necessary to obtain statistical results by using confidence intervals for unknown proportion based on binomial sampling. The calculation of confidence intervals can be straightforward using normal approximation based on central limit theorem. However, the usual approximation is known to be poor for small sample size, or when the true proportion is close to Zero or One. This paper will summarize some usual methods to calculate confidence intervals for single proportion and the difference of two proportions. It also demonstrates various calculation methods through SAS PROCs or other DATA steps for usual or limited situations.In clinical trial, it is often necessary to obtain statistical results by using confidence intervals for unknown proportion based on binomial sampling. The calculation of confidence intervals can be straightforward using normal approximation based on central limit theorem. However, the usual approximation is known to be poor for small sample size, or when the true proportion is close to Zero or One. This paper will summarize some usual methods to calculate confidence intervals for single proportion and the difference of two proportions. It also demonstrates various calculation methods through SAS PROCs or other DATA steps for usual or limited situations.	Statistics, Pharmacokinetics & Health Outcome (SP)	MSD R&D (China) Co., Ltd	China

CD11	Data Transparency and Sharing: Research Benefits, Risks and the Future	Matt Becker	Whether called data transparency or data sharing, there is a movement to give more researchers greater access to patient-level clinical trial data. The goal is to create an environment for innovation in clinical research. Join this presentation to discuss what is being done, including exploring the value to the overall health care system of creating a multi-sponsor environment that gives researchers access to larger pools of data.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	SAS	United States
DM02	Visualizing Clinical Trial Data	Matt Becker	Today, all employees at health and life science corporations may need access to view operational data. There may be visualization needs for a business analyst to compare clinical trial spend versus similar past trials; for a clinical research associate to easily see what research sites may need more monitoring; for a data scientist to quickly and easily explore adverse event data for outliers; for a medical writer to have graphical patient profiles; for a CEO to immediately have high-level dashboards of operational performance. In this presentation we will discuss SAS Visual Analytics and demonstrate the benefits of visualization for health and life science organizations.	Data Management & Validation (DM)	SAS	United States
MC01	Working with the global team	Cindy Song	As more and more global companies open their franchises in China, effective collaboration between the China team and the global team may be one of the most important factors to achieve operational success. If you are a SAS programmer working at the company's China site, do you often wonder: What does the global team want? How to work with the global team effectively? How to become a partner with the global team? This presentation aims to provide some insight to these questions.	Management & Career Development (MC)	sanofi	United States

CC09	Tips and Tricks about SAS Data Migration among Operating Platforms	Mina Chen	In general, SAS data (datasets and catalogs) created on an operating system is not necessarily accessible after being transferred to a different operating system. SAS provides multiple approaches in helping to migrate and access SAS data among different operating environments. There are constraints in some of these methods. For example, Cross-Environment Data Access (CEDA) does not support SAS catalogs and indexes other than datasets. The purpose of this paper is to provide an verview of basic techniques to move SAS datasets and formats catalogs between operating environments so data remain accessible afterwards. The focus will be on situations when moving data with customized formats from Windows SAS9.2 to Unix SAS9.2. The concept introduced is also applicable in different scenarios. The pros and cons will be elaborated.	Coder's Corner (CC)	Roche Product Development in Asia Pacific	China
PO12	Output flexible and customized Excel spread sheets from SAS data sets using Excel XP Tagset	Yangyang Li	In HE&OR studies, customers often not only want to view the report, but also be able to 'manipulate' the data, for example, to sort, filter, add up, and etc. And Excel is a popular tool that most customers can easily handle with. However, while many programmers are familiar with ODS RTF, PDF, HTML, they may find dealing with Excel format is not that an easy stuff. As Excel tool applies unique language rules, the interactive mechanism between SAS and Excel appears more complicated than others. This presentation demonstrates how to generate flexible and customized Excel spread sheets from SAS data sets using Excel XP Tagset. Using standard HE&OR deliverables as output examples, we will discuss how Excel XP Tagset works on customized headers, titles and footnotes, background, colors, font styles, frames, rules, cell borders, alternating rows and columns, and etc.	Programming Techniques (PT)	Novartis	China

PO13	Alert when one is not Alert: SAS Call Sound Function	Vamse Goutam, Palanisamy Mohan and Amarnath Vijayarangan	Multitasking is the order of the day and many SAS programmers work on multiple tasks simultaneously. For long running programs, the programmer assumes that his particular program might take certain amount of time, but in reality the program might get completed earlier or later than the expected time based on the load on server. The only way a programmer can check the completion of the program is by checking the log intermittently or by setting up an email alert, which can also be missed when the person is working offline. A prompt notification after the execution of the program can help and save lot of time for the programmer. SAS can alert the programmer through CALL SOUND function which can play music after a DATA step or a PROC step or program completion. The advantage of an alert function is that 1. Programmer is notified even when he/she is not glued with SAS environment and is held up with other tasks. 2. Sometimes when there are multiple users working on a project, the programmer sitting adjacent to the current programmer can also hear the alert and can act upon it and submit next task assigned to him when the actual programmer is not around 3. When combined with Scheduler this can also serve the purpose of an Alarm The purpose of this paper is to leverage the functionality of Call Sound function which would help in effective time and resource management	Coder's Corner (CC)	Genpact	India
AD02	A Visualization Tool Developed with Visual Basic .Net for Global SAS Macros Management	Stanley Wei	To facilitate programming activities and to achieve higher efficiency as well as quality, plenty of global SAS macros are often developed, which has been one of the must-haves for a mature organization and is also one of the key components for process optimization. However, how to efficiently manage/maintain those undreds of macros, to help users identify the right macros and use them correctly, is usually not an easy job, especially for new comers. To address this problem, a isualization tool was developed accordingly with visual basic .NET, which has user-friendly interfaces and could be acted as a central platform for global macros management and learning system for SAS programmers. This presentation will demonstrate the typical usages of this tool and how it helps users to make full use of global SAS macros in your organizations.	Application Development (AD)	, Novartis Pharmaceutic als (China)	China

SP04	MMRM: Macro for Selecting Best Covariance Structure with the Method of Interest	Linga Reddy Baddam and Sudarshan Reddy Shabadu	In clinical trial analysis, while handling longitudinal continuous data, there are very often cases that the Mixed Model Repeated Measures (MMRM) tool is used to deal with the continuous endpoints when a dependent variable is collected multiple times. It is usually up to the statistician to specify the criterion for dentifying the best covariance structure against the chosen model among all possible covariance structures arranged in particular order of interest, or in the way it has been specified in Statistical Analysis Plan and/or Protocol. In order to achieve this with the use of SAS, clinical programmers have to develop a program which dynamically checks the each covariance structure by order of interest, or in the way it has been specified in Statistical Analysis Plan and/or Protocol, and to produce the estimates and main effects information based on the best covariance structure selected for the given model, The features of the %MMRM macro are explicitly discussed further in detail in this paper.	Coder's Corner (CC)	inVentiv Health Clinical	India
SP06	Bayesian Augmented Control (BAC) Application by using 'Proc iml'	Zhuo Chen and Ju Chen	Bayesian statistical methods are being used increasingly in clinical research because the Bayesian approach is ideally suited to adapting to information that accrues during a trial, potentially allowing for patients receive better treatment and for statisticians plan optimal clinical trial design. Due to the limitation of budget control, patients' demographics or some other unforeseen reasons, sometimes a study cannot recruit sufficient patients, reach the minimum sample size requirement and detect the effect between control group and treatment group. In this situation, it becomes a task for statisticians to design an efficient experiment to make full use of the patients. Bayesian augmented control, known as BAC, has provided a way for statisticians to use the limited patients' number to get an enough power. By borrowing historical information from previous studies and publications, the sample size of control group will be increased, which result in the fact that more patients can be allocated into treatment group and an adequate power can be calculated. By applying 'proc iml' in SAS, BAC method can be implemented in SAS and pharmaceutical companies can reach the goal of saving patients' numbers as well as controlling budget.	Statistics, Pharmacokinetics & Health Outcome (SP)	Eli Lilly	China

CD10	Submission of Pharmacokinetics (PK) Data in a CDISC Compliant Format	Yu Zhu	The legacy Pharmacokinetic (PK) data are usually produced from different sources with different data format: sample collection in CRF, concentration result from Lab findings, and parameters from pharmacokineticist. This brings a lot challenge when preparing SDTM and ADaM datasets for submission. This paper introduces some of the challenges and solutions associated with mapping the concentration data and the calculation of PK parameters into SDTM (e.g. PC and PP) and subsequent creation of ADaM.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	PPD Inc.	China
CD04	An implementation of XSL-FO techniques to convert define.pdf from define.xml	Kyle Chang	It's getting more common and important for the electronic submissions of clinical data to include define.xml, which specifies the CDISC standard for providing case report tabulation (CRT) data definitions in XML format. Although define.xml has proven to be a useful mechanism can easily help regulatory reviewers to navigate transmission of CRT metadata, it is not able to provide original features (e.g., hyperlinks, bookmarks…etc.) while they're printed out. One solution is to generate a printable define.pdf document with the same content as the define.xml. The printable define.pdf file accommodates bookmarks and hyperlinks functionality for online review, and it can also be printed out for hardcopy review. Providing define.pdf documents is not only to have an easy way to review clinical data submission package, but also to fulfill submission requirements for sponsor and regulatory authority. This paper provides an approach that using Extensible Stylesheet Language Transformations (XSLT) template converting "define.xml" to formatting objects for easy transformation to "define.pdf".	Coder's Corner (CC)	PAREXEL International	Taiwan

CC03	use self-defined function to indent long AE terms and dynamically repeat SOC in each page	Mijun Hu	we have two common cosmetic problems in AE table to overcome, one is that preferred terms is too long to be present in one line so that it has to be wrapped to the next line, nevertheless the text-indent in the next line cannot be maintained. The other is that preferred terms pertaining to the same SOC display across multiple pages, which entails the need of repeating of SOC on top of each page. For the first problem, we already have a bunch of paper introducing macros to automatically indent wrapped AE terms and this time I want to accomplish this purpose by using a self-defined function because of several advantages. And using this function along with the aid of compute block in proc report, we can dynamically repeat SOC on top of each page regardless how many rows available to filled in each page.	Coder's Corner (CC)	Beijing Novartis Pharma Co., Ltd	China
CD07	Implementation in the CDSIC Tumor Domains	Junjie Shang	Assessment of the change in tumor burden is an important feature of the clinical evaluation of cancer therapeutics: both objective response and disease progression are useful endpoints in cancer clinical trials and in most studies the tumor burden is evaluated using the RECIST criteria. This paper will introduce how RECIST 1.1 data are streamlined in CDSIC since there comes up with 3 new SDTM tumor domains – TU (Tumor Identification), TR (Tumor Response) and RS (Disease Response). All tumor domains are finding structure and have a distinct purpose respectively. Moreover, they can be linked using additional linking variables and the connection can be established through RELREC domain. This paper will introduce how to implement these tumor domains and their relationship.	CDISC, Submission Preparation, Data Standards, and Regulatory Review (CD)	PPD	China
MC04	The Fourth Lie - False Resumes	Ernest Pineda and Tracy Turschman	The fourth lie - false resumes. Twelve years ago we were surprised to see an increase in the number of resumes which exaggerated the sender's breadth of hiring managers desk. In this presentation, Tracy Turschman speaking for Ernest Pineda, President of the Gerard Group will discuss measures his company has taken to validate the accuracy of resumes using pre-planned questions, inexpensive background checks, and industry knowledge. He will share experiences, observations, policies and tools that have helped his firm expose under qualified, and falsely represented candidates.	Management & Career Development (MC)	Vertex Pharmaceuticals	United States

PO05	Use SAS® as a Tool of Error Detection and Reporting for Risk-Based Monitoring in Clinical Trials	Ka Chun Chong, Ming Po Lai and Chung Ying Zee	Risk-based monitoring (RBM) could greatly reduce the cost of a clinical trial while protecting safety of a patient and quality of data. To improve the RBM efforts, SAS plays an important role in data management, risk assessments, and reporting applications. In this poster, we present how to use the basic tools of SAS to detect potential errors and report data management activities for different sites in centralizing monitoring. The utilization of SAS software in RBM is able to enhance the overall efficiency for monitoring activities.	Posters (PP)	Clinical Trials and Biostatistics Laboratory, Shenzhen Research Institute, The Chinese University of Hong Kong,	Hong Kong Special Administrative Region of China

DM03	Disclosure Requirements for Public Registries	Paul Ngai	A number of public registries require sponsors to register their studies prior to enrollment. Some registries such as ClinicalTrials.gov require results data to be disclosed for completed studies under the FDAAA Section 801 requirements. It is apparent that each registry has their own set of requirements and review process. The information posted on public websites may differ from registries. This presents some challenges for sponsors or principal investigators to ensure that all information posted to the public is accurate and consistent. Before we tackle the accuracy and consistency of data posting, we also need to know what the requirements are for registrations and disclosures. Such as: Who Is Responsible for Registering Trials and Submitting Results? Which Trials Must Be Registered and Have Results Submitted to ClinicalTrials.gov? When Do I Need to Register and Submit Results? Are There Penalties If I Fail to Register or Submit Results? The biggest question is 'Who within your organization is responsible for aking sure that you are compliant?' INTRODUCTION AUTHORS' PERSPECTIVE We are a group comprised of disclosure specialists, data managers, medical monitors, medical writers, lab clinicians, and bio-statistical programmers. We developed our business to support sponsors and academic institutions to fulfill registration and disclosure requirements for public registries. We provide training and back office support in the	Data Management & Validation (DM)	Xogene Services	United States

SP09	Extend SAS by R	Derek Li and Helen Wu	Figures, simulations, and new statistical methodologies have become increasingly important and needed in pharmaceutical industry. Even though SAS is a powerful leading statistical analysis software in pharmaceutical industry, it is still not realistic to depend only on SAS to deal with all figures, simulations and new thodologies. Therefor extend SAS by some other tools are needed and there are several possible ways to extend SAS. One attractive option is to extend SAS by R, a free statistical environment which offers a wide variety of statistical and computing techniques. This paper will share the knowledge about how to extend SAS by R and illustrate corresponding application using graph programming.	Programming Techniques (PT)		China
PRIM	The Value of Visualization for Clinical Trials Researchers	Wenjun Bao	Statistics plays an essential role in clinical trial research. Even before a trial starts, principles of experimental design in statistics are used in trial design (e.g., sample randomization, confound elimination, and data bias minimization) to collect quality data. During data collection, the risk-based monitoring methods and processes provide mechanisms to assess data quality in real time from all clinical trial sites. These methods and procedures enable researchers to identify potential problematic sites and to improve the reliability of the data. After data collection, more statistical procedures and models are applied to further analyses and studies in drug safety and efficacy. Statistical methods and procedures are also needed to investigate the potential fraud and fabricated data. Perhaps due to lack of appropriate statistical knowledge and experience, some clinical investigators could feel overwhelmed by the amount, type, diversity, and complexity of clinical trial data. Biostatisticians may likewise struggle with the communication gap between statistical interpretation and clinical relevance. We have developed a series of statistical visualization tools in JMP Clinical, which are designed for statistical needs in the whole clinical trial life cycle. Through its many interactive visualization and graphic functionalities, JMP Clinical enhances the abilities of clinical researchers to understand and communicate the statistical approaches, effectively process complex data, and present meaningful results in the clinical trial study. This paper also presents clinical trial results through the novel interactive visualization, graphics, and tables, with common industry and FDA standards.	Statistics, Pharmacokinetics & Health Outcome (SP)	SAS	United States

PO14	Building a Partnership: Constructing a global team between a US Sponsor and a Chinese CRO	Jeanina Worden and Jasper Jiang	There may be many reasons for a sponsor to decide to work with a CRO but no matter the reason both teams always want to ensure a successful collaboration. Careful planning prior to the study work beginning is an important step towards this goal in any situation, no matter where the companies are located, but when they are in different countries planning becomes imperative. Whose SOPs will be followed? How will issues be communicated? What are the responsibilities of the leads within each company? By discussing, and coming to agreement, on these types of questions before study work starts, the teams avoid slowdowns due to confusion, miscommunications and under realized expectations. To avoid these issues, the Santen and Rundo teams have worked together to construct a solid plan, prior to study work getting underway, to clearly set expectations, anticipate challenges and develop processes to mitigate identified risks. This paper is intended to describe the steps taken and the working model for the partnership that resulted from these discussions.	Posters (PP)	Santen, Inc	United States