Welcome to Gaithersburg

Dear Attendees

Welcome to Gaithersburg, settled in 1765 as a small agricultural settlement known as Log Town, near the present day Summit Hall on Ralph Crabb’s 1725 land grant Deer Park. The northern portion of the land grant was purchased by Henry Brookes, and he built his brick home “Montpelier” there, starting first with a log cabin in 1780/3. This 1,000-acre tract became part of the landmark IBM Headquarters complex built on the then new I-270 Interstate Industrial and now Technology Corridor in the late 1960s-1970s. Benjamin Gaither married Henry’s daughter Margaret, and Benjamin and Margaret inherited a portion of Henry’s land prior to Henry’s death in 1807. Gaither built his home on the land in 1802. By the 1850s the area had ceased to be called Log Town and was known to inhabitants as Gaithersburg. [Wikipedia]

We are here to learn about metadata – that is data about data. What we call metadata represents “an underlying definition or description” of data. That is, metadata summarizes basic information about data. In our information-overwhelmed world, metadata helps us find information using technology. For example, a hemoglobin lab value is an example of basic clinical data. Metadata would describe this data as a value, containing a number and recording a hemoglobin result.

A metadata repository is simply a database that contains metadata. It provides a consistent and reliable means of access to data. The repository itself may be stored in a physical location or may be a virtual database, in which metadata is drawn from separate sources. Data standards are needed to enter metadata into a database and make it useful. Semantic interoperability, or the ability of computers to exchange data without ambiguity, is the end result. Systems bound to metadata can more efficiently implement end-to-end data life cycle processes.

At today’s PhUSE Single Day Event, speakers will present on metadata, metadata repositories and applications built to utilize both. We have a wide variety of presenters who will help you understand metadata’s promises and realities.

Frank, Theo, and Alex
Gaithersburg Single Day Event
Co-Chairs 2016

Your host city

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Oncology combination therapies
AstraZeneca is investigating combinations of biologic and small molecule therapies for the treatment of cancer. These combinations target the tumour directly and some help boost the body’s own immune system to induce tumour cell death.

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Frank Senk
AstraZeneca

Thejo Annareddy
AstraZeneca

Alex Batkhan
MedImmune

AstraZeneca is investigating combinations of biologic and small molecule therapies for the treatment of cancer. These combinations target the tumour directly and some help boost the body’s own immune system to induce tumour cell death.
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### Keynote Speech

**09:00–09:15**

**Keynote Speech**

Névine Zariffa  
AstraZeneca VP Biostatistics

**Biography**

Névine Zariffa was born in Cairo, Egypt and was raised in Montreal, Canada. After her training at McGill University and at the University of Waterloo (Mathematics and Statistics), she began her career as a statistician supporting agricultural research before moving to Philadelphia to join SmithKline Beecham in 1991, which went on to become GlaxoSmithKline. She joined AstraZeneca in November 2011 and is currently VP and Head of Biometrics and Information Sciences in Global Medicine Development.

Over the last 25 years, Névine has amassed a wealth of experience in her specialist area and also in driving strategic programs. She has supported early and late-stage clinical development and marketed products – primarily in the area of cardiovascular and metabolism – and has led global teams of quantitative experts across many quantitative disciplines. Névine has also led, or played an integral part in, numerous strategic initiatives, working with company colleagues, medical associations, academics and other groups (both PhRMA- and FDA-sponsored) to enhance the value of quantitative sciences beyond the traditional role of designing, analyzing and interpreting clinical trials. Névine has been a statistical reviewer for The Lancet and is the co-author of over 25 publications in peer-reviewed biostatistics and medical journals. She is happily married and currently based in Cambridge, UK.
### Metadata-driven, Standards-based Clinical Analysis and Reporting Environment

**Abstract**

The FDA binding guidance documents for the industry regarding study data standards further support broader acceptance of CDISC standards in the clinical research area. In addition to the regulatory requirements, biopharmaceutical companies and CROs are realizing the benefits of using CDISC standards as the baseline operational model. In order to fully realize standards benefits and minimize perceived acceptance barriers, the Metadata Repository (MDR) system that can support creation, maintenance and governance of standards must be in place.

At the same time, the mandate for a high-performing, open and flexible analysis and reporting environment has always been present in the biometrics community.

In order to address the increasing internal demand in these areas, AstraZeneca and MedImmune launched a program with the task of delivering a metadata-driven, standards-based clinical analysis and reporting platform that enables industry best practices for storing, integrating, managing, transforming, analyzing, validating, and reporting information in a regulatory-compliant manner for all AstraZeneca science units and MedImmune.

The program has made significant progress to date in terms of addressing challenges in system design, process support and business alignment. This progress and these challenges and solutions are shared in depth in the presentation.

**Biographies**

**Alexandr Hromcenco**

AstraZeneca  
Alexandr Hromcenco has about 20 years' experience in clinical research and development, specializing in statistical programming, development of clinical information standards, business development and business enhancement projects for biometrics. Currently, Alexandr is a Director of Infrastructure Projects at AstraZeneca, late-stage development, and leads the implementation of the iCARE project. He has an MS in Computer Science and an MBA with a focus in Finance and Management.

**James Miller**

AstraZeneca  
James Miller has held several roles in the AstraZeneca clinical programming department over the last two decades, predominantly in oncology and clinical data standards. He currently serves as Standards Leader within the Standard Development and Maintenance Team of the programming department. As such, he is responsible for leading the development of standards, providing guidance to various stakeholders on the use of standards, and the implementation of standards-related technologies. James holds a BS in Economics and an MBA.

### Metadata-driven Analysis – How Users Can Benefit from Metadata

**Abstract**

This presentation will describe the concept of metadata-driven analysis and taking part in metadata repositories as a means to simplify the daily work of scientists when analyzing clinical research study data and how analysis tools should take advantage of metadata repositories. Using metadata is usually seen as a benefit to systems and only indirectly to users. An often-overlooked advantage of metadata repositories is the potential to simplify user interfaces and workflows for data analysis when information captured from metadata repositories is incorporated into analysis tools. This presentation will briefly introduce the concept of metadata-driven analysis and then in detail discuss the differences between a commonly used standard tool for PK analysis and a modern cloud-based approach that incorporates metadata to increase efficiency and productivity.

**Biography**

**Peter Schaefer**

Validated Cloud Applications  
Peter is founder and CEO of Validated Cloud Applications – a start-up company developing cloud-based solutions for data management and pharmacokinetics analysis and reporting for clinical trials based on the CDISC standards. As a volunteer, Peter is actively involved in the CDISC and PhUSE community. Previously, he worked as Director of Product Management at Certara – a company that provides software products and consulting services to the biotech and pharma industry. Earlier in his career, Peter worked in software development as a programmer and manager for very different industries, ranging from automotive to military and aerospace, including the pharmaceutical industry. He holds a master's degree in mathematics and computer science and a Ph.D. in Engineering from German universities.
How to Find the Best MDR Solution for Your Organization

Kevin Lee
Clindata Insight

Abstract
Are you satisfied with the current Metadata Repository (MDR) solution strategy at your organization? Are you looking for a more efficient, beneficial MDR platform or to be more educated in the crucial factors of MDR solution?

Metadata repositories (MDRs) become very essential for life sciences industries to store and manage standards (e.g. CDISC and company-specific standards) and terminologies. However, many organizations are struggling with current metadata repository solutions because of version controls of standards, instability within the systems, resistance of study teams, and other issues.

This presentation will elucidate common challenges, concerns, and typical user complications encountered during the MDR process and demonstrate various solutions to these frequent issues. It will also introduce some variables to consider in the MDR selection process – defining the business objectives of the MDR solution, Proof of Concept (POC) and the evaluation of MDR functionalities of different solutions. Finally, the paper will introduce the MDR implementation process, including Systems Development Life Cycle (SDLC) and integration of MDR into in-house systems (e.g. SAS and EDC).

Biography
Kevin Lee, M.S., is Director of Data Science at Clindata Insight and a very active data-driven solution supporter, using computing analytics, standards metadata development and governance and data integration. Kevin is also a current member of the CDISC data standards team and the PhUSE semantic data model team. He has presented more than 30 papers at the various conferences. Kevin earned an M.S. in Applied Statistics at Villanova University following a B.S. from the University of Pennsylvania. He is a lifetime learner who loves to learn and share. He also loves watching sports like football, baseball, and soccer despite his wife’s attempts to encourage other hobbies such as landscaping and home improvements.

The Chicken and the Egg Dilemma: Why Metadata Solutions have Struggled

Chris Decker & Ian Fleming
d-Wise

Abstract
Over the last five years the industry has thrown around the acronym MDR (metadata repository) like it will be the solution to solving the world’s problems, allowing us to push-button the end-to-end clinical trial. We have worked with many customers over the last decade helping them implement the CDISC standards and associated processes and tools and have come to the realization that this is not a technology problem but is more fundamentally centered around the chicken and egg dilemma. You can’t develop and/or implement a solution if 1) the underlying model cannot support the end-to-end workflow you are trying to achieve and 2) there is no focus on the end user and what they really need to accomplish within the clinical data flow.

The first challenge the industry faces in implementing a metadata management solution is the lack of realistic expectations about the underlying standards you are trying to manage within the technology. For example, with almost every customer we work with we hear the infamous requirement “The system shall provide end-to-end traceability”. How can this ever be accomplished when the standards you are implementing don’t support traceability? Companies must define their operational model that supports the workflow and not necessarily the model being asked for.

The second challenge is the lack of focus on the end user and what they really need to accomplish their job. Instead, our industry lets IT do to the user what they really need to accomplish within the technology. For example, with almost every customer we work with we hear the infamous requirement “The system shall provide end-to-end traceability”. How can this ever be accomplished when the standards you are implementing don’t support traceability? Companies must define their operational model that supports the workflow and not necessarily the model being asked for.

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Biographies
Chris Decker is Vice President, Life Sciences Practice at d-Wise, a technology and process consulting company focused on helping companies improve what they do every day through process improvement, enabling technology, and leveraging data standards. In addition, he serves as FDA PhUSE Liaison Director and is a member of the Computational Science Steering Committee. Prior to his current role, his experience in technology and pharma companies has led him to want enabling companies for a healthier world.

Ian Fleming has been working in pharma/biotech for over 15 years as a statistician, programmer, project lead, process analyst, and tool implementer. He currently works at d-Wise in the role of Director of Life Sciences. His motivation comes from his desire to improve experiences in pharma and healthcare for patients, doctors, and all people involved in the drug development process.
Automating CDISC Deliverables through Processing Metadata

Abstract
Many companies in the pharmaceutical and biologics industry have been developing and implementing metadata repositories for use in governing each company’s use of data standards. In addition, the push by regulatory agencies for electronic submissions has driven those same companies to provide the data from these metadata repositories as part of their submission as a DEFINE.xml. This is all in support of good documentation, which is a good thing.

What if you could do more with metadata than just supporting the DEFINE.xml file? There have been a number of “solutions” attempted to incorporate programming code into the MDR to do some automation, but with minimal success. With the use of CDISC standards and evaluating the use of these tools, it is possible though to deliver standardized domains without having to write code (or at least a minimum amount of code). This presentation will guide you through the concept of using metadata to create these CDISC-compliant domains.

Biographies
Paul Slagle is the Director of Global Data Standards at inVentiv Health. He has direct responsibility for assuring all work at iVH requiring CDISC compliance conforms to those standards. Paul has been working in CDISC since early 2003 when introduced to a “near SDTM” approach by data management. Since then he has been involved in CDISC deployment across a number of clinical trials, including oncology, that have been used in submissions. Paul's team covers NA, the EU, and India in support of iVH analytics teams in those locations. Paul is also a 30+ year SAS programmer and has presented at a number of user conferences including PhUSE.

Eric Larson is a Standards Engineer at inVentiv Health. He has been working with CDISC standards since early 2003. Eric is responsible for working with study and therapeutic leads to mentor the projects in the proper use of CDISC standards. This includes study planning, CDISC training and guidance, and CDISC compliance reviews. Eric is also involved in the development of tools to assist teams in the use of CDISC including automated templates that are CDISC-compliant, specification compliance tools, and submission documentation (including DEFINE).

Moving from Data Collection to Data Visualization Analytics: Leveraging CDISC SDTM Standards to Support Data Marts

Abstract
Data from clinical trials supports a wide range of clinical, safety, regulatory, and analytic groups who all share the same basic need: to efficiently access, analyze and review the data. When clinical data from multiple studies are combined into a “data mart” and linked to visualization and analytical tools, data consumers are able to efficiently find the information they need to make informed decisions.

The raw data as collected in individual studies will vary (at a minimum) based on the specific collection system and forms used. Due to that variability, a foundational step in creating a data mart is to ensure that the data from across studies has a consistent, standard format. We will share our experience leveraging CDISC SDTM standards to support data marts containing data from many studies across several therapeutic areas.

Practical considerations related to ensuring 1) that the SDTM implementation is consistent across studies, 2) that the data made available will support all consumer needs, and 3) that the data will be made available as needed by the consumers, will be discussed. Thoughts on how the industry shift towards integrating CDASH standards into collection forms and the emergence of therapeutic area standards will benefit the future state of visualizations and analytics based on data marts will be shared.

Biographies
Steve Kirby, JD, MS, is a Senior Manager in Global Statistical Programming at Chiltern. He has spent his last 10 years in the industry focused on optimizing the implementation of CDISC data standards. He is a member of the CDISC AdAdM team, AdAdM PK sub-team and is active in PhUSE Working Groups.

Terek Peterson, MBA, is Senior Director of Global Statistical Standards at Chiltern, with over 20 years’ experience performing statistical analyses for a wide range of clinical trials. He participates as a member of the CDISC Advisory Committee, the AdAdM team, the AdAdM v1.2 Authoring Co-Lead and sub-teams such as AdAdM compliance, AdAdM integration, AdAdM metadata, AdAdM questionnaire, and PhUSE FDA/CSS Working Groups. Terek is an experienced and frequent presenter on standards and SAS programming-related topics.
14:00–14:30
CDER, Regulatory Science Informatics and Metadata: What We’ve Learned
Salvatore Pepe
CDER, FDA

Abstract
There have been considerable efforts directed at the establishment and characterization of metadata for regulatory science information submitted to the FDA. These efforts are especially helpful in facilitating efficient and standardized regulatory review of new drug and biological product applications within CDER. The regulatory science information that CDER generates during the regulatory review of these product applications – including discipline reviews, correspondences, and other internal documents – exists largely in archived documents and tends to be unstructured. A great opportunity exists to systematically collect, transform, and analyze this information in a way that could be fed back to review teams in order to facilitate thorough and efficient drug review. We present our approach to developing a Regulatory Intelligence System (RIS), our explorations into metadata management, and lessons we have learned along the way.

Biography
Lieutenant Commander Salvatore Pepe graduated from Northeastern University School of Pharmacy in 2010 with his PharmD. He was commissioned in the US Public Health Service Commissioned Corps in August of that same year. Through the CDER Academic Collaboration Program, he was assigned on a long-term training billet to pursue his master’s in pharmacoepidemiology at the University of Florida (UF). Upon graduating from UF in 2012, he started working on-site at the White Oak campus of the FDA for the Rare Diseases Program (RDP) in the Office of New Drugs. One key responsibility of his was to utilize the DASH database to develop methods of measuring impact of Rare Diseases Program activities. In doing so, he became involved with, and developed an interest in, the various opportunities for knowledge management within the Agency. In July of 2015, he transitioned to a new role with the Knowledge Management Team at the Office of Translational Sciences (OTS).

14:45–15:15
Implementing End-to-End Data Standards from a Metadata and Technology Perspective
Michael Goedde
PAREXEL

Abstract
The expression “end-to-end” is a broadly used term in our industry. However, when put in the context of data standards only very few approaches seem to hold up to the true meaning of it. This presentation will provide a high-level overview of how to implement an end-to-end solution, not only from a metadata perspective but also from a technology perspective. Traditionally, data acquisition (CDASH), mapping (SDTM), and analysis (ADaM) are handled by different data operation departments. The result of this segregation quite often creates a disconnect in the flow of metadata between these departments, despite having implemented CDISC concepts on a company level. In addition, the lack of supporting technologies such as a clinical MDR (Metadata Repository) and an integrated SCE (Statistical Computing Environment) can hinder a comprehensive and sustainable data standards implementation. Attendees will be presented with a possible approach on how to break the typical silos around CDISC implementation and how to use an MDR/SCE ecosystem as a supporting tool set.

Biography
Michael Goedde is a Certified Clinical Data Manager with more than 23 years’ experience in the pharmaceutical industry. He started his career in 1990 at Hoechst, a predecessor company of Aventis, in Frankfurt (Germany), working as a Study and Project Data Manager. After supporting numerous submissions and leading programs through all stages of clinical development, Michael then chose to join the Aventis Headquarters in Bridgewater, New Jersey as a Global Project Data Manager and Global Therapeutic Area Lead in 2001. In 2005 he accepted an offer to join Kos Pharmaceuticals in Weston, Florida as an Associate Director of Clinical Data Management, where he was an integral part of building a new CDM department. After the takeover of Kos Pharmaceuticals by Abbott Laboratories in 2007, Michael accepted the position of Director of CDM at Human Genome Sciences (HGS) in Rockville, Maryland, where in addition to leading the CDM department he played a pivotal role in bringing the first lupus drug in more than 50 years to market. Michael had spent more than five years at HGS when GSK initiated another takeover. At that point in time he decided to take a break from work and travel around the world with his wife and two children for nine months, before accepting a position as Senior Director of Clinical Data Management at MedImmune in Gaithersburg, Maryland, in July of 2013. At the end of 2014 he was offered a position at PAREXEL International as Vice President for Clinical Database and Statistical Programming, which is the position that he currently holds.

Michael holds a degree in computer science and is a recognized member of the Society for Clinical Data Management (SCDM). He has presented and chaired sessions on numerous occasions at SCDM and other conferences, including an invitation by the FDA to present on CDM best practices for future and current FDA inspectors as part of the center’s bioresearch monitoring course. Michael also discovered the exponential function that delivers the most consecutive prime numbers in a row.
CDISC Share: The Road Ahead

Sam Hume

Abstract
SHARE is the metadata repository (MDR) for the CDISC standards. CDISC is improving the computability of its data standards by transitioning the development, management, and dissemination of standards metadata to leverage capabilities being developed in SHARE. Creating processes and tools to automate content loading into SHARE is ongoing. A suite of tools in the SHARE ecosystem have been developed to support metadata creation, loading, quality control and electronic access via eSHARE and a forthcoming application programming interface (API). Many versions of CDISC foundational standard specifications and their implementation guides, semantics in the form of controlled terminology packages and the BRIDG domain analysis model, and therapeutic area standards, have already been loaded into SHARE. Today, SHARE changes the way standards are created and consumed, but SHARE will have an ongoing impact on CDISC’s overall approach to standards development and governance.

This presentation will provide an update on the current state of SHARE and the benefits it provides today. It will also provide insights into the future development and direction of SHARE and how this might impact those implementing the CDISC standards.

Biography
Sam Hume is a partner and Principal Consultant at Next Step Clinical Systems. In his current assignment at CDISC, he performs the role of Head of Data Exchange Technologies, where he leads the SHARE API project and co-leads the XML Technologies Team. Sam has over 20 years’ work experience in clinical research informatics. Previously, he worked as Vice President of SHARE Technology and Services at CDISC, Director of IS Architecture at AstraZeneca, VP of Technical Operations at Phoenix Data Systems, and Chief Technology Officer at CB Technologies. Sam is currently completing his doctorate in healthcare informatics.
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Looking Forward

June
- Denmark SDE
  June 15th
- India SDE
  Hyderabad
  June 18th
- EU CSS
  Basel, Switzerland
  June 21st-22nd

July
- China SDE
  Beijing
  July 8th
- USA SDE
  Deerfield, IL
  July 21st
- India SDE
  Trivandrum
  July 30th

August
- USA SDE
  Frenchtown, NJ
  August 4th
- Japan SDE
  Tokyo
  August 4th

October
- PhUSE Annual Conference
  Barcelona, Spain
  October 9th-12th

November
- China SDE
  Shanghai
  November 4th
- USA SDE
  Durham, NC
  November 10th

December
- India SDE
  Mumbai
  December 3rd

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