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EVENTS LIST

# Good Clinical Data Management Practices (GCDMP)

**Date :** Feb 22, 2018 - 09:00 AM - Feb 23, 06:00 PM

**Event URL :** http://www.sfbayeventslist.com/events/good-clinical-data-management-practices-gcdmp-feb-2018-1516374671

**Organizer :** GlobalCompliancePanel

**Venue :** Four Points by Sheraton Los Angeles International Airport

**Location :** 9750, Airport Blvd
Los Angeles, CA, USA, ZIP: 90045

**Why should you attend:**

Good clinical data management (CDM) is paramount for a successful research. After all, Garbage In, Garbage Out (GIGO).

CDM is involved in all aspects of collecting, processing, and interpreting information. There are many types of computer applications and database systems to support data collection and management. However, there are elements of Good Clinical Practice that apply across the board.

Review and approval of drugs or devices by regulatory agencies requires the assumption that the data presented are valid and reliable. Integrity of the data is paramount to ensure confidence in the results and conclusions you will make.

This seminar is based on FDA E6 GCP Guidelines which are the basis of effective data quality management. Even if your research is not FDA regulated, the information you learn in this course will help to ensure a robust data collection and management plan.

The information conveyed in this course will also assist investigators in setting up processes for smoother data monitoring and auditing.

Examples of CRF's and required documentation will be presented. Data cleaning techniques will also be demonstrated. Additionally, this workshop will provide you with the knowledge and tools needed to assure GCDMP's that hold up when the inevitable deviations from protocol occur.

**Who will benefit:**

- Study Investigators
- Data managers
- Data processors
- Statisticians
- Site Personnel
- Clinical Research Associates
- Clinical Project Managers/Leaders
- Study Sponsors
- Professionals in pharmaceutical, medical device, clinical and biotechnology research who oversee or work with data collection and management
- Staff in the above fields who work with data collection/management and require training in GCDMP.
- Compliance auditors and regulatory professionals who require a knowledge of GCDMP in assessment of study protocols and reports

**Day 1 Schedule**

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Lecture 1 (90 Mins):

**GCDMP: The Reasons and The Requirements**

- GIGO = Garbage In, Garbage Out. Why we need good practices in data management
- Presentation and overview of FDA GCP Guidelines on data management
- NIH Policy (SOP 15, 17, 19)
- 21 CFR Parts 11, 312.62, 812.140
- Presentation and overview of SCDM guidelines for GCDMP

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Lecture 2 (90 Mins):

**Elements in Developing a Data Management Plan**

- Choosing a vendor and outsourcing
- Data privacy and protection of subject data
- Quality Assurance and Quality Control
- Monitoring and auditing of data
- Errors and Corrections
- Storage and Transfer of Data

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Lecture 3 (180 Mins; Afternoon of Day 1):

**Study Set-Up**

- Essential documents

    - Prior to Study Commencement
    - During Conduct of the Trial
    - After Completion/Termination of the Trial
- CRF design and development (paper/e-CRF)
- Database build and testing
- Edit Checks preparation and testing

**Day 2 Schedule**

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Lecture 1 (90 Mins):

**Study Conduct**

- Data Entry
- Discrepancies, errors, corrections
- Data Cleaning (preparation) and Coding

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Lecture 2 (90 Mins):

**Study Conduct (cont'd)**

- (MedDRA and WHODDE dictionaires)
- Data Review and Quality Control
- Data Transfer

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Lecture 3 (90 Mins):

**Study Closeout**

SAE Reconciliation

- Quality Control
- Database Lock
- Electronic Archival
- Database Transfer
- Enhancing Reproducibility

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Lecture 4 (90 Mins):

**Monitoring Visits**

- What to expect during a monitoring visit
- Elements for Establishing a Corrective Action Plan
- Question and Answer Session

**Elaine Eisenbeisz**
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Owner and Principal Statistician, Omega Statistics

**Elaine Eisenbeisz,** is a private practice statistician and owner of Omega Statistics, a statistical consulting firm based in Southern California. Elaine has over 30 years of experience in creating data and information solutions for industries ranging from governmental agencies and corporations, to start-up companies and individual researchers.

In addition to her technical expertise, Elaine possesses a talent for conveying statistical concepts and results in a way that people can intuitively understand.

Elaine's love of numbers began in elementary school where she placed in regional and statewide mathematics competitions. She attended University of California, Riverside, as a National Science Foundation scholar, where she earned a B.S. in Statistics with a minor in Quantitative Management, Accounting. Elaine received her Master's Certification in Applied Statistcs from Texas A&M, and is currently finishing her graduate studies at Rochester Institute of Technology. Elaine is a member in good standing with the American Statistical Association as well as many other professional organizations. She is also a member of the Mensa High IQ Society. Omega Statistics holds an A+ rating with the Better Business Bureau.

Elaine has designed the methodology for numerous studies in the clinical, biotech, and health care fields. She currently is an investigator on approximately 10 proton therapy clinical trials for Proton Collaborative Group, based in Illinois. She also designs and analyzes studies as a contract statistician for nutriceutical and fitness studies with QPS, a CRO based in Delaware. Elaine has also worked as a contract statistician with numerous private researchers and biotech start-ups as well as with larger companies such as Allergan and Rio Tinto Minerals. Not only is Elaine well versed in statistical methodology and analysis, she works well with project teams. Throughout her tenure as a private practice statistician, she has published work with researchers and colleagues in peer-reviewed journals. Please visit the Omega Statistics website at www.OmegaStatistics.com to learn more about Elaine and Omega Statistics.

Please contact Marilyn Turner: Phone: +1 929 900 1853  Email: marilyn.turner [a] nyeventslist.com for registrations

**Event Categories :**