

## Data Management Webinar and Online Learning Program

**Week 1, Session 1: Monday, December 3<sup>rd</sup> 2012**  
9:00 – 11AM EST

### Modules covered

*Lesson 1* - Development of DM Plans

*Lesson 2* – SOPs, WI and Forms

*Lesson 3* – Elements of a Robust DM System

### Learning Objectives

- Understand the importance of the Data Management Plan
- Understand the contents of a Data Management Plan
- How to develop and maintain a Data Management Plan
- To identify the elements of a robust DM system
- To understand how the elements can work together to fulfill many needs
- To understand the GCP definitions and principles that apply to DM systems
- What are SOPs, WIs, and Forms?
- How to develop SOPs, WIs, and Forms?
- How should they be managed?

**Week 1, Session 2: Thursday, December 6<sup>th</sup> 2012**  
9:00 – 11AM EST

### Modules covered

*Lesson 4* – Validating and Documenting DM Systems

*Lesson 5* – Case Report Form Design

*Lesson 6* – Design of Data Entry Systems

### Learning objectives

- What are the elements of validation?
- What documents are needed for validation
- Use design standards to create Case Report Forms
- Use Case Report Forms to help manage your study
- Meet regulatory requirements when designing Case Report Forms
- How to create tools to aid the design of systems
- How to create documentation to support systems
- How to prepare for rigorous validation of systems

## Data Management Webinar and Online Learning Program

**Week 2, Session 1: Monday, December 10<sup>th</sup> 2012**  
9:00 – 11AM EST

### Modules Covered

*Lesson 7* – Form Processing Entry and Filing

*Lesson 8* – Data querying Design

*Lesson 9* – Data Cleaning and validation

*Lesson 10* – Generating, Tracking, Reviewing and Resolving Queries

### Learning objectives

- How to process and keep track of Case Report Forms (CRFs)
- How to use tools like the Batch Flow Sheet and database audits to track forms
- How to create a filing system
- Understand where data errors can occur
- How to systematically identify data errors
- Know the components of the systematic data cleaning process
- What are the different types of queries
- How to design query tracking tools
- How to update the database and file queries

**Week 2, Session 2: Thursday, December 13<sup>th</sup> 2012**  
9:00 – 11AM EST

### Modules Covered

*Lesson 11* – Data set creation and quality assurance

*Lesson 12* – Database lock

*Lesson 13* – Archiving and Warehousing

### Learning objectives

- What are the different types of database freezes?
- What tools help you manage the data set creation process?
- What types of quality assurance can you apply to the data you create?
- What is database lock?
- When should database be locked?
- When should database be unlocked?
- What are the differences between Archiving and Warehousing?
- What information should be archived and warehoused?
- How to manage and control archived and warehoused information