**Course Description**

This course provides an excellent introduction to clinical data management in the pharmaceutical industry. Its focus on processes and their rationale renders it ideal for the new data manager and to other individuals who wish to learn basic clinical data management skills and the function of clinical data management in the drug development process.

**Who Should Attend**

- Staff of Pharmaceutical Companies, Contract or Independent Research Organizations whose function is to review, correct, enter, or manage data, with less than one year of experience in that function.
- Individuals who desire a basic understanding of the function of clinical data management in the drug development process.

**Instructor**

Denise G. Redkar-Brown

**You Will Learn To**

- Understand the drug and study development process
- Identify the roles and responsibilities of the clinical research team
- Discuss the protocol design and development process
- Review the CDM Start-up activities/documentation
- Analyze case report form design, data tracking and collection, data entry and capture
- Discuss data review, validation, and queries
- Comprehend the rationale of the MedDRA dictionary
- Understand quality control and quality assurance
- Discuss database lock and release
- Understand adverse event reporting and reconciliation
- Identify CDM issues associated with managing mega-trials and CROs

**Interactive Exercises**

- Core Definitions and Concepts • To “Split” or Not to Split • Identifying Data Checks

---

**Course Outline**

**Day One: 8:30 a.m. – 5:00 p.m.**

- **Introduction to Drug Development**: Good clinical practice – purpose and history; roles and responsibilities of the FDA/ICH; phases of drug research and development
- **Overview of Clinical Data Management**: Data management core processes and data flow; roles and responsibilities within clinical data management; interfaces with other disciplines within clinical research and development
- **Protocol and Design**: Good clinical study; steps in protocol development; designing a clinical trial; protocol elements and modifications
- **Study Start-Up – A Clinical Data Management Perspective**: Study documentation; data handling manual; annotated case report form and database design; remote data management
- **Case Report Form Design and Development**: Standard and study specific case report form modules; organization of a case report form; CRF design guidelines; data collection methods; CRF tracking; data capture, flow and entry; remote data capture

**Day Two: 8:30 a.m. – 5:00 p.m.**

- **Data Review and Validation**: Data errors; frequently encountered problems; identifying and developing data checks; data queries
- **Coding**: Purpose of coding; common coding dictionaries; computerized coding (autoencoding); coding philosophies
- **Quality Control and Quality Assurance**: Roles of quality control and quality assurance; audits and documentation
- **Database Release and Lock**: Study close-out and database release; lock and unlock
- **Adverse Event (AE) Reporting**: Definitions; describing and documenting AEs; collecting AE data

---

**Course Dates and Locations**

**August 19-20, 2008**
San Diego, CA
Courtyard San Diego Downtown
Course #: SIMD0808
$1,495 by July 11
$1,695 after July 11

**October 21-22, 2008**
Boston, MA
Hyatt Regency Boston
Course #: SIMB1008
$1,495 by September 12
$1,695 after September 12

**December 2-3, 2008**
Chicago, IL
Embassy Suites Hotel Downtown
Course #: SIMC1208
$1,495 by October 24
$1,695 after October 24

**Registration**

- **ON-LINE**: www.barnettinternational.com
- **FAX or MAIL**: Submit Registration Form (back cover) with Payment to Barnett Customer Service

For assistance, CALL (800) 856-2556

**Hold This Course at Your Company! Call (800) 856-2556 for more information.**

**Accreditation**

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 15 hours (1.5 CEU) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation.

Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 778-000-07-012-L01-P. Released: 10/07.