



*Second Program  
In The Series*

# Implementing A Clinical Trial Program

## **Course Introduction**

### **Sponsor Obligation**

- Introduction
- Investigator Selection
- Investigational Product
- Financial Disclosure
- The Second Step

### **Protocol Development**

- Introduction
- Types of Clinical Research Studies
- Protocol Concept (Optional)
- Contents of a Clinical Research Protocol

### **Data Management**

- Introduction
- Regulatory Requirements
- Case Report Forms
- Designing Case Report Forms
- Tips for Designing CRFs and EDRs
- Ensuring Quality
- CRF/EDR Monitoring and Review

### **Adverse Event Reporting**

- Introduction
- Definitions
- Responsibility for Reporting
- Safety Reports
- DNA Containing Studies (RAC/OBA & IBC)

### **Investigator Responsibilities**

- Introduction
- Investigator Qualifications
- Statement of Investigator Form (Form FDA 1572)
- Adequate Resources
- Informed Consent
- Adverse Event Reporting
- Study Product Accountability
- Study Compliance
- Records and Reports

## **Course Authors**

Carol Nash

Michael Carter, MD, RP

Sr. Director, Clinical Safety & Pharmacovigilance

URL Pharma, Inc.