Case Report Form (CRF) Design and Requirement

March 21-22, 2014
Beijing, China

One of the most valuable assets in clinical research is trial data. The quality and integrity of clinical data is directly impacted by the case report form (CRF) instruments used to collect them. A data collection tool whether paper or electronic, is only valuable if it collects data accurately and efficiently. Data collected that is not relevant to the protocol or does not answer the protocol endpoints results in delays and increased cost. This workshop is designed to provide the unique opportunity to hear from a variety of perspectives on the challenge and goal of successful CRF design. The topics will cover general introduction of CRF development, CRF layout designing, placement of CRF elements, CRF annotation process and standard CRF development strategy etc. The interactive small group discussions will be included for attendees to have an opportunity to discuss real-life problems and solutions in day-to-day CRF design.

LEARNING OBJECTIVES

- ICH/GCP requirements to (e)CRF development
- General rule and challenge of CRF procedure
- Relationship of protocol with CRF development
- Relationship of CDISC standards to CRF development
- Layout and placement of CRF elements
- Requirements of CRF annotation and completion instruction
- General tools used in the CRF development
- ePRO regulation and procedure
- Elements of subject diary development
- QA/QC practice during the CRF development

WHO SHOULD ATTEND

- Clinical project management
- Clinical data professionals
- Clinical research monitors
- Clinical study professionals
- Clinical research associates
- Quality assurance and quality control professionals
- Clinical researchers and study coordinators
- CRF/data standardization professionals

PROGRAM CHAIRPERSONS

Daniel LIU, PhD
Director, China Development, Medidata Solution Worldwide

DENG Yazhong, MBA
Head of Clinical Data Analysis and Reporting Organization (CDARO), Covance

PROGRAM COMMITTEE:

WANG Hongwei
Manager of data manager, Data Analysis and Reporting Organization, Covance

FAN Yiteng
Senior Manager of Data Management, Department of Clinical Operation , Sanofi

HOST:

PARTNER:

Clinical Data Management Group of China (CDMC)

Metropolis Tower 7th Floor | Room #766 | No.2 Haidian Dong San Street | Zhongguancun Xi Zone | Haidian District, Beijing 100080, China
Tel. +86.10.6260.2240 | Fax. +86.10.6260.2201 | www.diachina.org | DIA@diachina.org

DAY ONE | FRIDAY, MARCH 21

07:30 – 08:30 REGISTRATION

08:30 – 08:45 WELCOME AND OPENING REMARK

08:45 – 09:45 SESSION 1

REGULATORY PERSPECTIVES AND GENERAL RULE ON CRF DEVELOPMENT

The CRF is an essential component of every clinical trial, a road map linking the protocol to a study results. This session will describe what ICH/GCP requirements are and what rule and challenge are facing to the CRF design.

- ICH/GCP requirements in the management of CRF development
- General principles and specific perspectives of CRF development
- Efficient management of resources for CRF development
- Relationship of protocol to the CRF designing
- Key points of CRF development for a specific clinical trial
- Differences of CRF design between paper and electronic CRF

09:45 – 10:30 SESSION 2

GENERAL LAYOUT OF CRF DESIGN

CRF design requires unique and art views. This session will more focus on getting the layout of CRF for data collection that is right the first time.

- Basic CRF elements
- Data field and font infrastructure in CRF
- General format types of CRF forms
- Unique page and form distribution in CRF design
- PI signature field in paper and e-CRF
- CRF translation

10:30 – 10:45 TEA BREAK

10:45 – 12:00 SESSION 3

CRF DEVELOPMENT PROCESS

Management of CRF development is involved with all aspects of resources. Also, there is a difference of paper CRF from electronic CRF development. This session will present the general process and expectations of CRF development related to the business resources.

- The process and timeline for paper- and e-CRF development
- Role and Responsibility for p/e CRF development
- Group discussion/practices

12:00 – 13:30 LUNCH BREAK

13:30 – 15:00 SESSION 4

CRF MODULES, FORMS AND TEMPLATES

The complex process of CRF design can include everything from the module development process, form design and translation to data management, standard and web expertise. As part of the CRF contents, subject diary is a unique procedure to be considered. This session will provide a variety of information to consider when developing and designing CRF.

- Introduce the CRF Modules/Forms and anatomy of a form
- Go though common CRF modules/Forms, at least but not limit to:
  - DEMOGRAPHICS — DM
  - INCLUSION/EXCLUSION CRITERIA – IC/EC
  - QUESTIONNAIRES – QS
  - LABORATORY TEST RESULTS – LB
  - MEDICAL HISTORY – MH
  - PHYSICAL EXAMINATION - PE
  - VITAL SIGN – VS
  - PREGNANCY TEST – PT
  - ADVERSE EVENTS – AE
  - DRUG EXPOSURE – DE
  - CONCOMITANT MEDICATIONS – CM
  - TRIAL SUMMARY PAGE - TS
  - DV
- Introduce the differences of CRF modules/Forms/Templates between oncology study and others.
- Interactive practices

15:00 – 15:15 TEA BREAK

15:15 – 17:00 SESSION 5

DATA STANDARDS/CDASH OF CRF DEVELOPMENT

CDISC has been extensively used as a data standard in the trial data procedure. CDISC standard is closely related to the CRF data sets and fields. This session will then cover the most popular format of data sets per CDISC standard, i.e., CDASH and STDM. The type of data standard library will be addressed as well.

- Type of standard libraries: core standard and project specific
- CDASH Overview
- The implement CDASH for CRF development
- STDM introduction
- Relationship and challenge between CDASH and STDM

17:00 – 17:30 END OF DAY ONE

DAY TWO | SATURDAY, MARCH 22

08:30 – 09:15 SESSION 6

QA/QC PROCESS FOR CRF DEVELOPMENT

Rational quality management in the CRF development should always address all stages of CRF lifecycles. To establish, implement, and maintain a system that allows the delivery of CRF product with the quality attributes appropriate to meet the needs of sponsors, health care professionals, regulatory authorities (including compliance with approved regulatory filings) and other internal and external customers. This session will review the effective monitoring and control QA/QC systems for process performance and CRF quality, thereby providing assurance of suitability and capability of trial data collection processes.

- Quality Assurance (QA) process for CRF: no data points missing as per protocol
- Quality Control (QC) process for CRF: no issues/typo
- Evaluation procedure of CRF quality
- Quality control post CRF development

09:15 – 10:00 SESSION 7

POPULAR TOOLS OF CRF DESIGN

A CRF design can be completed via several ways by CDM professionals. This session will introduce commonly used tools used to develop CRF.

- Adobe InDesign (Pagemake)
- Microsoft Publisher, Microsoft Word, etc
- Demonstration of tools

10:00 – 10:15 TEA BREAK

10:15 – 12:00 SESSION 8

CRF ANNOTATION (aCRF)

When a clinical data management processes a CRF, he should appropriately understand how to handle the data collected in the CRF. Thus, CRF annotation is essential to guide CDM to interpret and program definitions of data set recorded in CRF. This session will cover the concept and standard practice of the annotated CRF.

- Significance of CRF annotation and how to use the a-CRF
- Methodology of CRF annotation
- Role and Responsibility for CRF annotation
- The different process of CRF annotation for p/e-CRF
- Case examples of CRF annotation
- Interactive practice

12:00 – 13:30 LUNCH BREAK

13:30 – 14:15 SESSION 9

REGULATION AND PROCEDURE OF ePRO DEVELOPMENT

In clinical trials, a PRO instrument can be used to measure the effect of a medical intervention on one or more concepts (i.e., the thing being measured, such as a symptom or group of symptoms, effects on a particular function or group of functions, or a group of symptoms or functions shown to measure the severity of a health condition). This session will give a general introduction what consideration involved in the ePRO development and implementation.

- Regulatory requirement of ePRO application
- Validation and reliability of PRO instrument
- Redesign of an ePRO instrument into CRF page
- ePRO training standard prior to the CRF implementation
- ePRO elements to be consideration
- ePRO administration and completion procedure
- Subject diary design

14:15 – 15:00 SESSION 10

CRF COMPLETION GUIDELINES

The CRF completion is critical for investigator staffs to collect and transcribe the trial data into CRF, which is directly related to the data quality and integrity of trial results. The education of CRF completion seems essential. Thus, a clear and reliable instruction how to complete the data collection per CRF requirement is designed to ensure the accurate and adequate data in CRF records. This session will cover the concept and standard practice regarding the development and training of CRF completion.

- CRF completion process including approval per GCP standard
- Requirements of CRF completion instruction
- General instruction and page specifications of CRF completion
- Training and project guidance of paper and/or e-CRF completion
- Subject diary instruction

15:00 – 15:15 TEA BREAK

15:15 – 17:00 SESSION 11

CASE STUDIES AND INTERACTIVE PRACTICES

This session will give a time and event flow chart usually shown in the protocol and require a hands-on interactive practice how to correct errors in the CRF design and convert the data points from the protocol into CRF design.

- Group discussion
- Group presentation

17:00 – 17:30 SUMMARY AND WRAP UP