• A **CROS Academy** course

Thursday, **10th May** 2018 | 9:00 – 18:00

Clinical Data Management 2.0:

*Fundamentals and New Skills of today's **Clinical Data Manager***

| Madrid, Spain

For further information:

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Introduction

Implementing a clinical data strategy can be complicated for any clinical trial Sponsor. The truth is there is no "manual" in place which describes how to prepare a clinical data strategy. Clinical data management plays a fundamental role in any company's biometrics strategy. Data Managers were once associated with "Data Entry Clerk", and the role usually required no formal training and had no defined role within clinical research. Thanks to regulatory guidelines such as Good Clinical Practice (GCP), regulatory authorities such as EMA and audits and inspections, the role of the Data Manager has changed.

The Data Manager now has more of a stake in the requirements for data collection, data accuracy and quality. Therefore, it is now important for the entire clinical study team to understand data management processes and the role of data management in the overall biometrics picture.

This course aims to cover the fundamentals of data management processes in the GCP environment such as CRF design, data management plans, data validation specifications, coding of medical terms and data quality. Within these processes, this courses stresses the importance of data standards such as CDASH and covers the basics of implementing these standards during database build.

The course will also touch upon the connection between data management and Risk-Based Monitoring strategy.

Course Objectives

After this course, participants should be able to:

- Understand key clinical data management terminology
- Better interpret the evolving role of the Clinical Data Manager within the biometrics team
- Have a solid understanding of CRF design (both paper and EDC) , data management plans, coding and cleaning of data
- Understand Coding dictionaries
- Comprehend the role of clinical data management in Risk-Based Monitoring

Official language of the course

English

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For whom is this course designed?

- Data Managers
- Biostatisticians
- Medical Writers
- CRAs and Monitors

And

- Heads of Clinical Operations, Development or R&D, Medical Directors and Medical Affairs professionals, Heads of Biometrics who wish to stay up to date about the Clinical Data Management development and about Data Manager's role

Agenda

09:00 – 09:30	**Welcome & Registration**
09:30 – 10:00	GCP Basics including recent GCP E6 R2
10:00 – 11:15	CRF Design: Paper vs Electronic CRF
11:15 – 11:30	**Morning Coffee Break**
11:30 – 12:15	CDASH Basics
12:15 – 13:15	Database Setup Tasks and Responsibilities
13:15 – 14:00	**Lunch**
14:00 – 15:15	Data Management Plan Development
15:15 – 15:45	Data Quality in Clinical Trials: cleaning and holistic data review
15:45 – 16:00	**Afternoon Coffee Break**
16:00 – 16:45	Coding of Clinical Terms
16:45 – 17:30	Data Management and Connection Risk-Based Monitoring (RBM) Strategy
17:30 – 18:00	**Wrap-up and Q&A session**

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Lecturer's bio

Monica Pimazzoni, *Director Clinical Data Management, CROS NT*

Monica joined CROS NT in 2010 as the Head of Clinical Data Management after more than 20 years in the data management department of GlaxoSmithKline. In 2012, Monica became the Head of Database Programming as well and is accountable for managing workload and headcount as well as ensuring clean, accurate and complete clinical data in accordance with the project plan and ICH/GCP guidelines.

Monica began her career in data management in 1987 as a data monitor in the data monitoring unit of GlaxoSmithKline. She later became a Data Manager and then a Senior Data Scientist for Clinical Pharmacology Statistics and Data Sciences. In 2007, Monica became Therapeutic Program Manager for Clinical Pharmacology Data Sciences leading data management activities across a compound/disease area through all stages of development.

In her experience, Monica has a broad understanding and in depth knowledge of the clinical development and data management process. She has been involved in hundreds of studies across her career, covering Phases I-IV and observational studies and numerous therapeutic areas. In CROS NT alone, she has done extensive work in Neurosciences, Respiratory and Oncology. Her study experience has also included numerous EDC studies and she is well experienced in the implementation and database setup for EDC as well as hybrid EDC/paper studies.

About CROS NT e CROS Academy

As a global Contract Research Organization (CRO), CROS NT enhances clinical trial outcomes and optimizes vendor oversight with data-driven services and solutions. From study design to clinical study reporting, CROS NT's services include biometrics and data science (data management, biostatistics programming and analysis), medical writing, pharmacovigilance, regulatory consultancy and clinical project management and monitoring.l.

CROS Academy | Established as a specialist biometrics CRO, CROS NT launched CROS Academy as a training branch to provide a series of classroom trainings and webinars in our areas of expertise including biostatistics and clinical data management. We also offer in-house, tailored training for companies with specific needs.

www.crosacademy.com

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To register for the course you can fill in and send the **registration form** to crosacademy@crosnt.com or directly **register online** https://2018-clinical-data-management.lsacademyevents.it/orders/new

Registration Fees

- ☐ **Early bird: € 640,00** until 26/04/2018
- ☐ **Ordinary: € 750,00**
- ☐ **Academy – Public Administration: € 450,00**

A discount will be applied for the registration of 3 or more colleagues of the same company. Please contact crosacademy@crosnt.com

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form.

Bank transfer payable to:

EasyB S.r.l.
Via Roma, 20 - 24022 Alzano Lombardo (BG)
P. **IVA 03633040161**
Banco BPM - Filiale di Carobbio Degli Angeli
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Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. CROS NT and the organiser EasyB reserve the right to postpone or cancel an event, to change the location of an event or to alter the lecturer for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

The course will proceed with a minimum of 6 participants.

Should this number not be reached, the registered participants will be notified at least one week prior to the commencement of the course.

The secretarial office reserved the right not to accept registrations not compatible with the course's target audience (please read the section "For whom is this course designed?" in the leaflet).

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

Date _____ **Signature** _____

For further information, please contact the secretarial office

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