



CDISC SDTM in Oracle Clinical 5.1

Venue

RELICO Neuss office, 20 min from Düsseldorf airport.

Booking

Request availability by e-mail, if place available we will send you a booking template, then book course by fax or mail.

Cancellation policy

By fax or in written, two weeks before workshop free of charge, two week - one week before workshop 50% of fee or exchange against place on next course, less than one week before workshop full fee or possibility to send replacement without additional costs.

Prerequisites

Oracle Clinical base workshop and data management and standards experience.

Duration

1 day course.

Class times

27 November 2017, Monday from 10:00-18:00

Price

Euro 700, incl. workshop material, excl. VAT, billing and payment before the course, accommodation and travelling not included.

Instruction Method

Instructor-led workshop including hands-on exercises.

Versions

Workshop material for OC 5.1 will be used, an OC 5.1 workshop database will be used. OC is developed in an evolutionary way, thus all functionality from previous versions is included in OC 5.1.





Description

The CDISC (Common Data Interchange Standards Consortium) Study Data Tabulation Model (SDTM) has recently become the standard for submitting SAS datasets to the FDA. It may also serve for exchange of data in the lifesciences industry.

One way for Oracle Clinical users to become CDISC SDTM ready could be to use their current global library (GLIB) set-up and their current extract views and to write a set of SAS transfer macros to convert their SAS datasets to the CDISC standards.

The other extreme is to set-up the GLIB and the study definition in Oracle Clinical as compatible as possible with CDISC SDTM to produce CDISC-compatible SAS datasets from within Oracle Clinical. The latter approach will be the topic of this course and can be of interest for companies that newly implement Oracle Clinical or that are in the process of refurbishing their GLIB and data definition standards.

Audience

Senior Data Managers and Global Librarians

Course Topics

- Creating CDISC SDTM compatible key templates
- How to handle extended attributes in the light of CDISC SDTM length 8 SAS names
- Define Medical Evaluation Types according to CDISC SDTM
- How to manage Thesaurus Validated Questions that have a SAS name length limitation of 7
- How to transfer the CDISC SDTM into the GLIB (mapping)
- Do horizontal or vertical modelling
- Necessity to adopt your CRFs
- Create CDISC SDTM compliant extract views in case of horizontal modelling with external views

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