Announcing the next CDISC ESUG Teleconference

Topic: HL7 and the link to CDISC

Date: 17th September 2009

The English Speaking CDISC User Group Committee would like to invite you to the latest teleconference on HL7 and the link to CDISC.

To enable us to plan for numbers (and to ensure we have enough phone lines) for this event you will need to register, please email registrations@esug.org.uk to sign up for this event by the 1st September 2009. Details on how to attend this event will then be sent to each registered user by 11th September.

Date: 17th September 2009

Time UK: 14.00 to 15.30PM
Time Europe: 15.00 to 16.30PM
Time USA: 09.00 to 10.30AM

Duration: 60 minutes presentations, 15 minutes Q&A.

Note: The meeting has been extended to 1 and 1/2 hours to allow for sufficient time to handle any technical issues getting the TC started.

Chaired By: Simon Hawken (member of the ESUG Committee)

Content:

Abstract: Clinical data are not flat and cannot be exchanged using flat two-dimensional files without significant loss of meaning. FDA is transitioning to a 'round view of the world' of clinical research and the CDISC-HL7 standards will help them get there. SDTM is here to stay but will transition from a standard submission format to a standard view of the data in support of simple analysis. At this session you will learn more about:

- How the CDISC-HL7 standard will benefit regulatory review of clinical research
- How will it impact on the SDTM standard?
- What is the CDISC-HL7 standard?
- Why do we need the CDISC-HL7 exchange standard?
- How is the standard being developed?
- When will the standard be available?
- When will the FDA implement it?

Presenter: Armando Oliva, M.D. (previously worked at the FDA)