

## **New for Interchange this year – User Discussion Sessions:**

An exciting development at this year's European Interchange is the introduction of:  
**User Discussion Sessions.**

CDISC have always known that the CDISC team leaders, their teams and, of course, the **USERS** of the standards are vital to the standards development process. The E3C will be facilitating the opportunity for discussion with the users based on some key questions raised by the teams. Special booths will be arranged and sessions split by either model or topic and will cater for up to 15 people per session.

Structured debate will be hosted by a CDISC subject specialist and a specialist note taker – but the material will come entirely from the **users**. This is your chance to freely discuss with your colleagues, how you are using the models, how they impact your ability to do your role (both constructively and positively) and how they impact the business process more holistically.

In order to aid preparation, please look at the series of questions below and **take these questions into internal meetings, within your companies in preparation** for the Interchange. Company representatives should then register for the event and can attend the sessions bringing those thoughts together in a shared environment. These thoughts will be discussed, collated and distributed to the appropriate CDISC groups.

We very much look forward to running the sessions and hope they provide a suitable basis for the CDISC User community to get involved more directly with CDISC.

## **Questions Sets**

### **Generic questions for SDTM/ADaM/CDASH/Terminology/ODM:**

- What are the adoption and implementation challenges with the model?
- What are the greatest risks behind using the model?
- What are the greatest benefits of using the model?
- Are you more or less efficient since your implementation of the CDISC standards? Please elaborate.
- What would be the most significant improvement which could be made in this area – if any
- What is in your opinion the best direction for the model and the team to take within the next 1-4 years?

**Generic questions for Integration:**

- What are the greatest benefits / challenges to an end2end adoption of the CDISC models into your company infrastructure?
- What are the major benefits of an embedded end2end solution
- In an end2end implementation where are the 'pinch points' – I.e. what are the most difficult challenges and which model are they associated with?
- Specifically, where are the greatest integration issues between the models

**Generic questions for PRG:**

- Are you using / implemented the model, if not, why not?
- How easy is the PRG model to implement? What are the challenges?
- What are the greatest risks behind using the model?
- What are the greatest benefits of using the model?
- What would be the most significant improvement which could be made in this area?
- What is in your opinion the best direction for the model and the team to take within the next 1-4 year?

If you have any further questions about these discussion groups or would like to express your intention to be involved, please contact:

Jason Housley [jhousley@shire.com](mailto:jhousley@shire.com) or Niels Both [nb@s-cubed.dk](mailto:nb@s-cubed.dk)