Summary on
OpenCDISC LIVE Forum
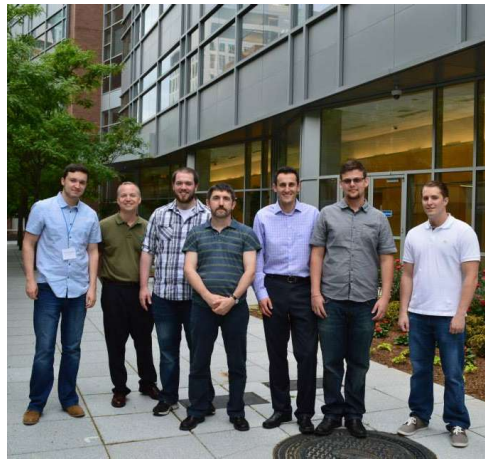
Boston MA, USA June 9th 2014

German CDISC User Group Meeting

16-September 2014

Darmstadtium, Darmstadt

Event Summary

- CDISC and FDA educational event

- Presenters: JumpStart, DataFit, Pinnacle21

- More than 100 attendees from Pharmaceutical and Biotec Industry and other Organisations (e.g. CDISC, FDA)

Event Summary

- **FDA JumpStart for the Modern Review Process**

  Learn about the new FDA Modern Review Process, JumpStart, DataFit, and why you should care

  JumpStart conducts a series of drug clinical trial data analyses early in the review process — to assess data composition, quality, analyses options and more

  At a high level, JumpStart helps reviewers:
  - Assess clinical trial data quality
  - Determine what types of analyses can be performed and what review tools can be used
  - Identify where there are gaps or inconsistencies in the data that may have an impact on the review

  -> JumpStarting Drug Review @FDA Homepage

- **Getting the most out of OpenCDISC Validator**

  Review best practices for configuring OpenCDISC Validator, including setting up and updating MedDRA and CDISC Controlled Terminology, and improving performance. Learn how to run OpenCDISC Validator from CLI, SAS, USB, and on Macs. And learn how to analyze and interpret OpenCDISC reports.

Event Summary

- **Using OpenCDISC to prepare for FDA submissions**

  Learn about the new FDA Study Data Technical Conformance Guide and what it's telling us about validation and the use of OpenCDISC. We'll also review the most common OpenCDISC messages and how to handle them.

  (**!**) Interesting presentation: The section on the common data issues and the slides are almost self-explanatory).

- **How OpenCDISC Enterprise improved our process and compliance**

  See a case study of how Biogen Idec has implemented OpenCDISC solutions to improve the processes for CDISC compliance and FDA submissions

  "Marketing" presentation to show benefits when switching from free OCV version to enterprise (licenced) OCV version.

- **Demonstration of OpenCDISC Enterprise**

- **Live Forum Discussion**

- Summary and Presentation slides available @
  http://www.pinnacle21.net/blog/open-cdisc-live-boston-recap

- Second event OpenCDISC LIVE
  @Novartis in East Hannover, NJ on Sep-9th-2014
  http://www.pinnacle21.net/blog/open-cdisc-live-new-jersey

- Third OpenCDISC LIVE event already planned:
  Gilead / 333 Lakeside Drive / Foster City, CA 94404
  Wed, October 8, 2014
  12:00-4:00pm

Creating Define.xml 2.0 with OpenCDISC
Webinar 12th + 14th-Aug-2014

- Demonstration on how to create define.xml v2.0 compliant define.xml file with OpenCDISC-validator

- Slides, Video and Q&A available @
  http://www.pinnacle21.net/blog/creating-define-xml-2-0-webinar-recap

  - Video: http://www.youtube.com/watch?v=8PzYO0YlO0I

  - Slides: http://www.pinnacle21.net/blog/wp-content/uploads/2014/08/creating-define-2.0-with-opencdisc.pdf

  - Webinar Q&A Blog: http://www.pinnacle21.net/blog/creating-define-xml-2-0-with-opencdisc-webinar-qa