CDISC User Group und PhUSE

mkeiten - Ab

5-September

Rohrbacher Str. 26

69115 Heidelberg

+49-6221-6051-0

info@analytical-software.de

CDISC and PhUSE

Overview & General Principles

- CDISC (Clinical Data Interchange Standards Consortium)
  - Since 1997, www.cdisc.org
  - Mission: "to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare"
  - Open, multidisciplinary, neutral, non-profit **standards developing** organization (**SDO**)
- PhUSE (Pharmaceutical Users Software Exchange)
  - Since 2004, www.phuse.eu
  - Independent, not-for-profit organization run by volunteers
  - Global membership organization (> 8000) for data managers, biostatisticians, statistical programmers and eClinical IT professionals
  - Works on projects relating to **standards implementation**

CDISC & PhUSE Collaboration

History

- Memorandum of Understanding (MOU)
  - Signed in Austin, TX on February, 19th 2015
  - Strengthening the partnership for the benefit of stakeholders conducting regulated clinical research and product development
- https://www.cdisc.org/CDISC-PhUSE-Partnership-Collaboration

PhUSE – a Collaborative Approach

Share – Contribute - Advance

- Food & Drug Administration (FDA)
- European Medicines Agency (EMA)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Clinical Data Interchange Standards Consortium

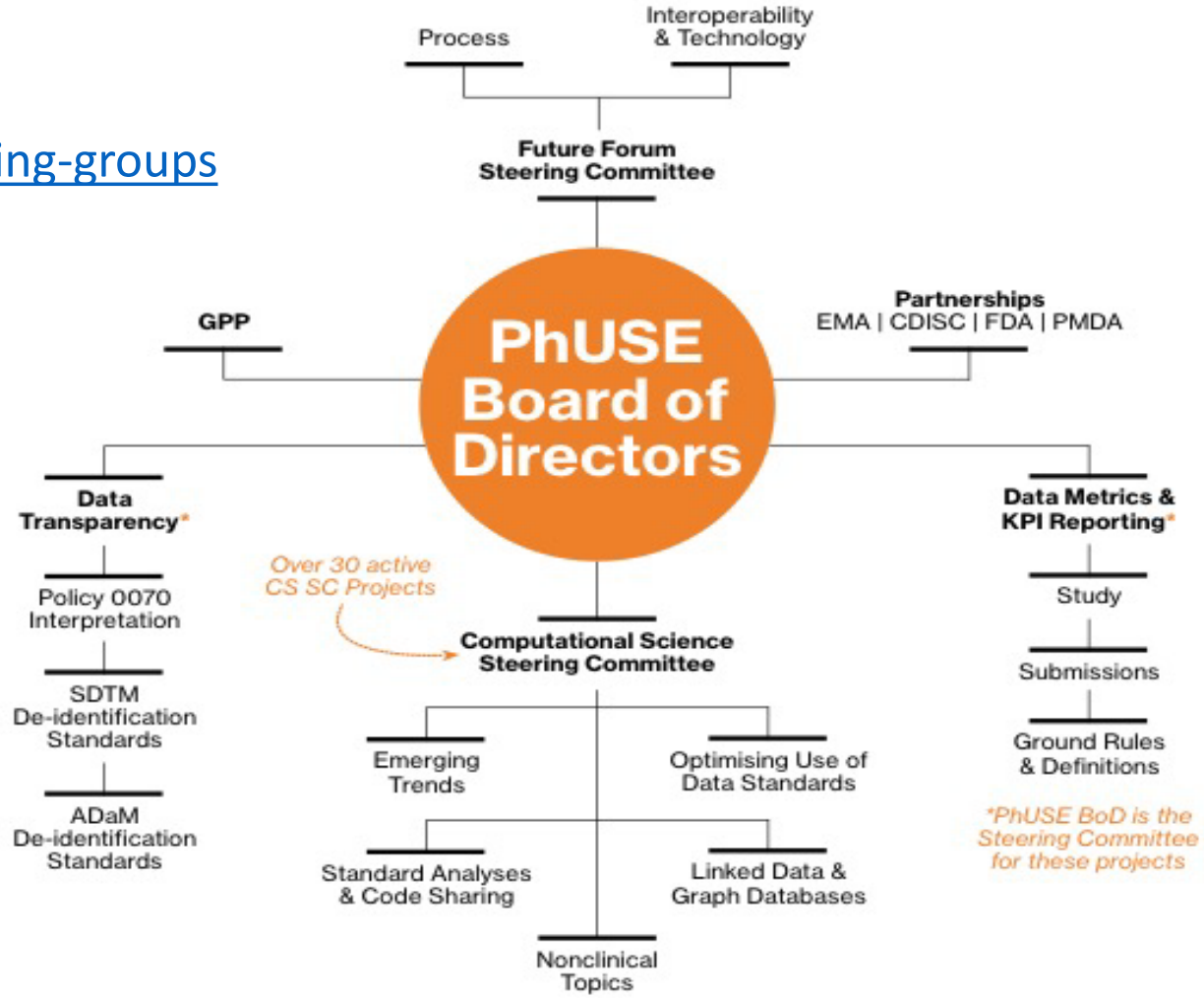
CDISC & PhUSE Collaboration

CDISC at the PhUSE annual conference

- CDISC & Industry Standards (CD) Stream **2007 – 2016**
  - Clinical Data and Metadata Standards developed by CDISC
    - explanation and interpretation
    - implementation: processes and tools
  - e-Submissions
  - Interaction with health authorities
- **2017**
  - Data Standards & Governance (DS) Stream
  - Standards Implementation (SI) Stream

PhUSE Working Groups

http://www.phuse.eu/working-groups



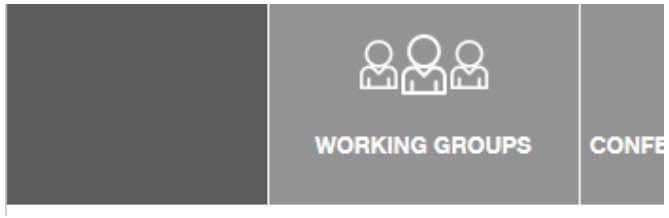
PhUSE CSS (Computational Science Symposium)

CS Working Groups since 2012

- Volunteers from major stakeholders
  - Academia
  - Pharmaceutical / biologics / device industry
  - Contract research organizations
  - Technology vendors
  - SDOs, specifically CDISC
  - Regulatory agencies, mainly FDA
- Open to anyone who wants to contribute
- all final deliverables are available on the website

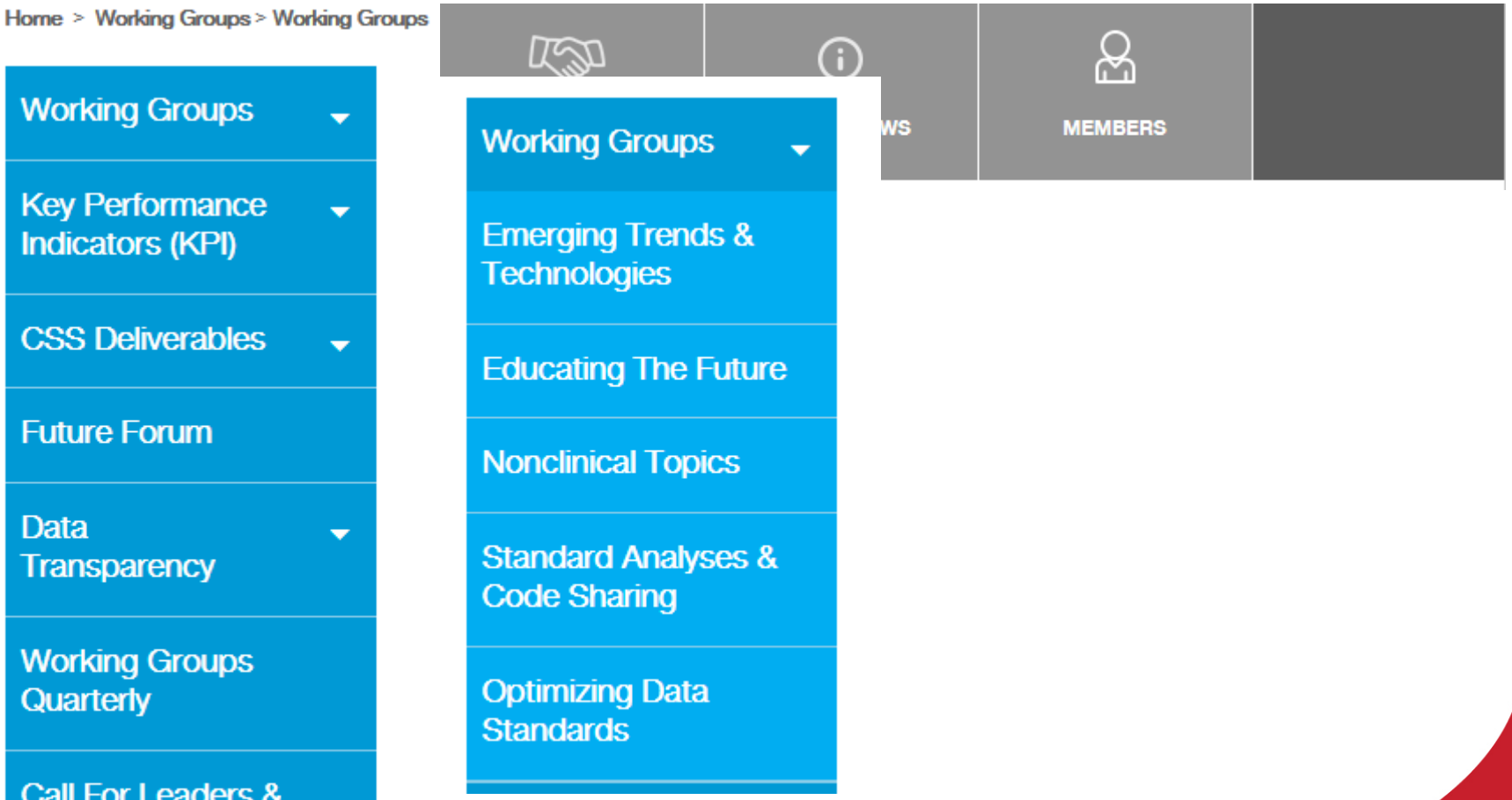
PhUSE – a Collaborative Approach

Share – Contribute - Advance



http://www.phuse.eu/working-groups

http://www.phuse.eu/css-deliverables



http://www.phuse.eu/optimizing-data-standards

CDISC & PhUSE Collaboration

A new era

”
CDISC needs PhUSE to succeed
“

100TH SDE RECAP

Frankfurt

CDISC & PhUSE Collaboration

Current leadership

- semi-regular meetings with David R. Bobbitt, the new CEO
- „many conversations between the CSS Steering Committee and CDSIC through Barrie Nelson and now Shannon Labout in particular relating to the CSS projects to ensure we are working together“

Latest collaboration initiative

CDISC - PhUSE Virtual Roundtable Discussion

- **Problem Statement:**
  Questionnaires, rating scales and other instruments may contain items that may be logically skipped or left unanswered. For example, an instrument may instruct the subject to skip to Question 5 when Question 1 is answered "no". Items that are logically skipped or left unanswered are typically not represented in SDTM. Regulatory agencies have been collaborating with CDISC to explore representing all items including those that have been logically skipped or left unanswered in SDTM. In order to maintain traceability, information about logically skipped items and/or items left unanswered would need to be collected in Electronic Data Capture (EDC) systems or Electronic Patient Reported Outcome (ePRO) devices.

- **Meeting Logistics:**
  Session 1: August 28th, 10:00 am - 11:00am EDT
  Session 2: September 11th, 10:00am - 11:00am EDT

Challenges & Summary

- Voluntary work
- Driven by areas of specific need & interest
- Documentation
  - not always reflecting latest status
  - subject to improvement / re-structuring
  - Improvements / draw-backs not always easy to find
- Staying up-to-date is a challenge and requires continuous investigation

Contact Information

Beate Hientzsch

beate.hientzsch@analytical-software.de

+49-6221-6051-180

+49-1761-6051-180

Otto-Volger Straße 1a, D-65843 Sulzbach

HMS Analytical Software GmbH

Rohrbacher Str. 26
69115 Heidelberg

www.analytical-software.de
info@analytical-software.de
+49-6221-6051-0

XING HMS auf XING: https://www.xing.com/company/hmsanalyticalsoftwaregmbh