



Standard Data Implementation and Validation

Tokyo, Japan

31st October 2014

A nighttime photograph of the Tokyo skyline. In the foreground, the historic, ornate red-brick Tokyo Station is brightly lit. Behind it, a dense cluster of modern skyscrapers is visible, their windows glowing with light. Several construction cranes are silhouetted against the dark sky. The word "Welcome!" is written in a large, white, sans-serif font across the center of the image.

Welcome!

PhUSE SDE in Tokyo

- Today's 1st of PhUSE event in Japan !
- Theme is “Standard Data Implementation and Validation”
- Discussion in Japanese

What is PhUSE ?

- What is PhUSE ?
 - Pharmaceutical Users Software Exchange
 - An independent Non Profit Organisation run by volunteers
 - Global group of programmers, statisticians, and data scientists
 - Vendor neutral, inclusive, and open
 - www.phuse.eu
- Mission
 - Provide platform for creating & sharing ideas, implementing tools & standards around data, and exploring innovative methods and technologies

Mission of SDE

- To take PhUSE to programming hubs across the world and to complement the Annual Conference by presenting new material and updated presentations from previous events.

Attention

- All mobile phones to silent mode, please

Announcement

- Agenda changed
 - 10:15-11:00
 - **OpenCDISC Community 2.0: An Expanding Toolset for the CDISC Professional**
 - Max Kanevsky (*Pinnacle 21*)
 - 11:00-11:45
 - **The Big Value of Collaboration Through the Global Activities of PhUSE**
 - Ippei Akiya (*ACRONET*)

Agenda

Time	Title and speaker
09:30 – 10:00	Registration
10:00 – 10:15	Welcome Yoshiteru Chiba
10:15 – 11:00	OpenCDISC Community 2.0: An Expanding Toolset for the CDISC Professional Max Kanevsky (Pinnacle 21)
11:00 – 11:45	The Big Value of Collaboration Through the Global Activities of PhUSE Ippei Akiya (ACRONET)
11:45 – 13:15	Networking Lunch
13:15 – 13:45	A Domain Specific Language for Accelerated SDTM and ADaM Implementation Ippei Akiya (ACRONET)
13:45 – 14:15	How can Effective Metadata Management Improve Speed and Quality of CDISC-based Clinical Research Kunihito Ebi (Fujitsu)
14:15 – 14:45	Considerations on Legacy Data Conversion to CDISC Standards for e-Data Submission for NDA in Japan Yohei Takanami (Takeda)
14:45 – 15:15	Collaboration between Sponsors and CRO's with Study Level Metadata Repository Masami Ohchi (ACRONET)
15:15 – 15:45	Break
15:45 – 16:30	Advanced Review with Electronic Data and Use of CDISC Standards in PMDA Yuki Ando (PMDA)
16:30 – 17:15	Panel Discussion
17:15 – 17:30	Closing Remarks Yoichi Higashibeppu (Eisai)

Event contributors

ACRONET

EPSGROUP

formedi The logo for formedi features a stylized graphic to the right of the word 'formedi'. This graphic consists of a grey chevron pointing to the right, with a blue arrow-like shape integrated into its right side.

 **sas**
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Takumi
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Acknowledgement

PhUSE	Japan Working Group
Ajay	Ippei
Nand	Beppy
Trudy	Koichi
	Akira
	Yoshiko
	Shinozu



Enjoy your conference!
Thank you

Tokyo, Japan, 31 October 2014