CDISC symposium in Tokyo, Japan

The Japan Agency for medical research and development (AMED) is delighted to announce the CDISC symposium co-hosted by University hospital Medical Information Network (UMIN) Center, in Tokyo, Japan, March 24, 2017.

The symposium is designed to promote public understanding of and getting familiar with CDISC standards. Since October 1st, 2016, PMDA (Pharmaceuticals and Medical Devices Agency, Japan) has begun to accept the submission of the electronic data of clinical trials in CDISC standard format. In academia as well as industry, it will become clearly essential to establish a R&D system compliant to the CDISC standards to take efficient steps to data collection from the early planning stages of clinical research to application for approval. We are particularly welcome to the academic researchers and physician scientists engaged in the field of clinical researches and investigator-initiated clinical trials.

AMED was established in 2015 to serve as an institution dedicated to improving medicine through R&D in Japan. Our goal is to fast-track medical R&D that directly benefits people not only by extending lifespans but also by improving quality of life. We support the initial exploratory investigator-initiated clinical trials and clinical studies to international standard (ICH-GCP-compliant). In August 2016, AMAD joined CDISC to strengthen and accelerate the CDISC implementation in academia.

General Information

- Date: March 24, 2017 (Fri) 13:00-17:40 (tentative)
- Location: MARUBIRU HALL and Conference Square
  2-4-1 Marunouchi, Chiyoda-ku, Tokyo Marunouchi Bldg. 7-8F
  Access: http://www.marunouchi.com/e/shop/detail/9504
- Capacity: About 300
- Registration: No attendance fee but registration is required.
  Please register online from the following website. (Japanese only)
  URL: https://krs.bz/amed/m?f=223
- Contact: Tatsuya MARUYAMA, Koichi SAITO
  Japan Agency for Medical Research and Development (AMED)
  Department of Clinical Research and Trials
  Tel: +81-3-6870-2229, E-mail: rinsho-chiken@amed.go.jp
- Hosts: AMED http://www.amed.go.jp/en/
  UMIN http://www.umin.ac.jp/english/

国立研究開発法人 日本医療研究開発機構
Japan Agency for Medical Research and Development

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March 24, 2017 (Fri) 13:00-17:40
MARUBIRU Hall and Conference
Language: Japanese

Program

(1) Welcome and Introductory Remarks

13:00-13:10 Makoto Suematsu, AMED

(2) CDISC standards in Japan

13:10-13:30 (2)-1. Current situation of CDISC standards in Japan

Mayumi Shikano, PMDA

13:30-13:50 (2)-2. Expectation for the clinical research based on the CDISC standards on academia

Yasushi Komiyama, JPMA

(3) CDISC overview

13:50-14:30 CDISC: Overview, Strategy and Roadmap, Focusing on Academia

Clinical Data Interchange Standards Consortium (CDISC)

Founder President and CEO Dr. Rebecca Kush

14:30-14:50 ✣✣✣✣ Break Time ✣✣✣✣

(4) AMED and CDISC

14:50-15:05 (4)-1. Outline

Yasunori Yoshida, AMED

(4)-2. Research Projects

15:05-15:25 ①Data standards creation pertaining to specific disease area available for drug development

Takashi Moritoyo, University of Tokyo Hospital

15:25-15:45 ②Networking application and validation for clinical research data collection system using CDISC standards based on the electronic health record system

Yasushi Matsumura, Osaka University

15:45-16:05 ③Data conversion of clinical study data standardized by SS-MIX into CDISC format

Masashi Okada, UMIN center

16:05-16:20 ✣✣✣✣ Break Time ✣✣✣✣

(5) CDISC Japan User Group (CJUG)

16:20-16:35 (5)-1. CJUG Activities: Introduction

Yoshiteru Chiba, UMIN center

(5)-2. CJUG Activities: Case report

16:35-16:55 ① Application report in Nagoya Medical Center

Toshiki Saito, NHO Nagoya Medical Center

16:55-17:15 ② Implications and challenges in academia

Shizuko Takahara, Kanazawa University

17:15-17:35 ③ Perspective on high-quality data generation leading to CDISC implementation

Yoshihiro Aoyagi, National Cancer Center

(6) Closing Remarks