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**Issue 1**

**PMDA Begins Pilot Project Requiring CDISC Standards**

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) released a statement on 2 September 2013, requesting that companies participate in a pilot, submitting electronic clinical study data to PMDA that has been "amassed and summarized according to the CDISC standards." This project, which is anticipated to be complete by the end of fiscal year, is to assist the PMDA in boosting the submission of electronic study data. PMDA officials will be presenting at the CDISC International Interchange in Bethesda on 6 November and the Japan Interchange on 5 December with more details on their strategy with respect to CDISC standards. For more details on the 2013 CDISC International Interchange and the 2013 CDISC Japan Interchange, please visit the CDISC website. PMDA also has a liaison to the Japan CDISC Coordinating Committee (J3C).

The Pharmaceuticals and Medical Devices Agency (hereinafter referred as PMDA) recognized the need for accumulating electronic study data and proposed to start the preparation in compliance with CDISC standards, SDTMs, ADaMs and Define.xml, from the next spring. Many Japanese companies and academia just face to transform their business, trials and studies' styles. DOT international Co., Ltd adapts CDISC standards formats and support global activities for both companies and academia.
We always keep up with the latest information and will attend the 2013 CDISC Japan Interchange.

## Our Activity for CDISC

In 2013, DOT international Co., Ltd joined a Gold Membership of CDISC.
We adapt CDISC standards as our business standard and implement all over our clinical study to the global standards. We have various experience with clinical studies using statistic soft SAS and one of our business policy is to conduct CDISC based on SAS technology. With this combined system we generate XMLs, map SDTM, Adam and conduct logical checks, audit trails, and so on. We also build EDCs with CDASH. We build global standard systems for our clients and customize it to reach our clients' specific requirement.
Our Liaison Department is well-prepared for global study and at the same time, our system is settled down according to worldwide standard. We firmly believe DOT is your best gateway for Japanese clinical study.

DOT INTERNATIONAL
*Dynamic Organization for Trials & treatments*

**Services**

- ✓ Building EDC with CDASH format
- ✓ Converting legacy data to CDISC format
- ✓ Making SAS macros for SDTM data converting
- ✓ Creating Difine.xml
- ✓ Validating Computer System

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