

May 11th, 2016

To the press:

A2 Healthcare Corporation  
Digital Media System Co., Ltd.

## A2 Healthcare and Digital Media System Co., Ltd. to cooperate on the eData application service

A2 Healthcare Corporation (Headquarters: Bunkyo-ku, Tokyo, President & CEO: Tadashi Katori; hereinafter "A2 Healthcare") and Digital Media System Co., Ltd. (Headquarters: Chuo-ku, Tokyo, President & CEO: Hiroji Emoto; hereinafter "DMS") reached an agreement to jointly develop solutions for CDISC and eCTD pertinent to electronic data submission of applications for approval.

CDISC and eCTD are increasingly in demand in Japan with the acceptance of electronic data submission to the Pharmaceuticals and Medical Devices Agency (hereinafter "PMDA") pertinent to applications for approval, which are expected to begin in October 2016, and the enforcement of electronic data submission for applications for approval starting in fiscal 2020. Furthermore, there are now increasing numbers of memoranda, notifications and other information released by PMDA that are required to cover items necessary for submission.

Therefore, A2 Healthcare, which is strong in CDISC-related services and the amount of information it holds, and DMS, a leading domestic company providing eCTD compilation services, have decided to jointly develop solutions for CDSIC and eCTD pertinent to electronic data submission of applications for approval.

- A2 Healthcare will accelerate and improve the quality of pharmaceutical and medical device development including CDISC-related services by integrating the following services:
  - SDTM data conversion and peripheral services;
  - ADaM data conversion and peripheral services;
  - Support services for standardization of data conversion; and
  - Consulting services on activities related to CDISC.
- DMS offers "premium eCTD compilation service" with "LORENZ docuBridge<sup>®</sup>" as its core emphasis, and it provides total support services from the initial application for marketing approval.
  - Reuse of eCTD and NeeS prepared overseas and in Japan;
  - Clinical study report (CSR) publishing services; and
  - PDF rendering services on responses to inquiry from PMDA and public document masking services

With the prospect that data in CDISC will be essential for applications for approval, A2 Healthcare has been, since its former organization under ACRONET, engaging in activities of CDISC Japan User Group from 2004, and as a CDISC member (Gold Member) from 2009, and has been actively involved in activities obtaining knowledge concerning CDISC and educating and enlightening people in the industry.

Meanwhile, DMS has been proposing the utilization of an eCTD compilation "system" since 2005 when eCTD applications started, in an effort to streamline time and costs in the pharmaceutical industry by supporting transformation of massive paper-based application materials to eCTD, which is becoming a global standard. In order to bring about such a prospect, DMS has been working with LORENZ Life Sciences Group since 2004 and localized its eCTD support system "docuBridge<sup>®</sup>.com" to create "docuBridge<sup>®</sup>.jp", which is suitable for local specifications in Japan, and furthermore, has been customizing "LORENZ docuBridge<sup>®</sup>", which is an upgraded and globally-compliant model, so as to make it easier for customers to use.

Upon the commencement of PMDA's acceptance of electronic data as mentioned earlier, the alliance between A2 Healthcare, which has abundant experience and a track record in CDISC and DMS, which is strong in eCTD-related services, will enable the creation of an application package in the shortest time possible before the submission of applications for approval so as to support a smooth application process.

[About A2 Healthcare] <http://www.a2healthcare.com/>

A2 Healthcare is a full-service CRO engaged in clinical development support services with 860 employees in Tokyo and Osaka. It was established in November 2014 through the merger between former ACRONET and former A2 Healthcare (i.e., former clinical development support arm of Asklep). A2 Healthcare is particularly strong in the development of anticancer agents and also drugs in the areas of the central nervous system and respiratory system, in addition to its conventional expertise in the area of lifestyle related diseases. It is now proactively implementing information technologies to streamline its clinical study process, using EDC as its core progressive solution along with RMB, eSource Data and other IT solutions. A2 Healthcare is also involved in many global studies through an exclusive partnership agreement with PRA Health Sciences, top 5 worldwide CRO.

[About DMS] <https://www.dms-jp.com/>

With development and sales of computer software as its core business, DMS has been providing integrated services for development, sales, and support of systems for newspaper and pharmaceutical industries, and it is committed to continuously evolve as a company that can meet the needs of its clients.

In particular, it has been engaging in an eCTD compilation system "LORENZ docuBridge<sup>®</sup>" with which it has been providing not only outsource services, but also total support services from the implementation of the system to CSV assistance, training, and maintenance.

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