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To the press:

A2 Healthcare Corporation  
Digital Media System Co., Ltd.

## **A2 Healthcare and Digital Media System to launch **eData application consultation services****

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") have since May 2016 been jointly deploying solutions for CDISC and eCTD services pertinent to electronic data submission of applications for approval. The two companies will now begin joint deployment of **consultation services in electronic application via Gateway.**

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 began 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.

As a series of operations, A2 Healthcare has experience with everything from attendance during interviews with the PMDA to creation of CDISC packages, provision of consultations on electronic data submission, and attendance during electronic data submission via Gateway. In addition, the company has a long track record and much expertise, the first-ever for a domestic CRO, in the reporting of acceptance by the PMDA of electronic applications, and the attendance of subsequent interviews with the Agency.

Meanwhile, DMS has been engaged in numerous eCTD applications, from 2005 when eCTD's original applications began, to today. When eCTD applications first began, the work of eCTD compilation was often done manually, with tools being used for part of the operations. Later, DMS cooperated with LORENZ Life Sciences Group of Germany to not only respond to regulation requirements in Japan, but to also realize system-based eCTD compilation work. With this setup, the company has offered real-time online review services to users who request outsourcing operations. Online reviews can make outsourcing services, which tend to become non-transparent, more visible; they can also accommodate last-minute replacements of documents immediately prior to application submission. These and many other services have

won the trust of numerous users, allowing the company to accumulate know-how in eCTD application operations to date.

Using such know-how as the basis, and with the goals of meeting the new CDISC standards planned in 2020 and realizing incorporation into eCTD v4.0, A2 Healthcare, which is strong in CDISC-related services and the amount of relevant information, has been working with DMS, which is Japan's leading company in eCTD compilation services, to offer services to respond to the diverse needs of pharmaceutical manufacturers towards the enforcement of electronic data submission for applications for approval starting in fiscal 2020. As an even more high-quality, high-value-added service, the companies hereby announce the joint offering of **a series of new operations pertaining to electronic data submission via Gateway, and consultations on these services**, thereby contributing even more to the development of new drugs.

- A2 Healthcare will accelerate and improve the quality of pharmaceutical and medical device development including CDISC-related services by integrating the following services:
  - Creation of CDISC packages and peripheral services
  - Support service in standardizing data conversion and peripheral services;
  - Consultation services in CDISC-related operations
    - ◇ Attendance during interviews with the PMDA
    - ◇ Service to support the construction of timelines up to submission of approval
    - ◇ Support service in electronic data submission via Gateway
  
- 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 format will be essential for applications for approval, A2 Healthcare has, since its former organization under ACRONET, engaged in activities of CDISC Japan User Group from 2004, participated as a CDISC member (Gold Member) from 2009, actively studied and amassed knowledge on CDISC, and vigorously implemented educational and awareness-raising programs inside the industry. The company therefore is proud of being one of the most experienced within the industry in terms of both track record and expertise.

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 long 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 an even smoother application process.

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

A2 Healthcare is a full-service CRO engaged in clinical development support services with 960 employees in Tokyo and Osaka. Ever since it was established in November 2014 through the merger between former ACRONET and former A2 Healthcare (i.e., the former clinical development support arm of Asklep), A2 Healthcare has remained particularly strong in the development of anticancer agents as well as 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 technology to streamline its clinical study process, using EDC as its core progressive solution, along with RBM, 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 4 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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