



Company name	<b>CAC EXICARE Corporation</b>
	<a href="http://www.exicare.com/">http://www.exicare.com/</a>
Name of Representative	President & CEO <b>Hisashi Takahashi</b>

**"CDISC Standard Datasets Creation Support Services" Launched in November 2015**

- Prior to the start of electronic study data submission in CDISC standard format for new drug application -

Tokyo, November 11 2015 - Business & Decision Life Sciences headquartered in Brussels, Belgium (COO: Peter Van Reusel, "BDLS") and CAC EXICARE Corporation headquartered in Tokyo, Japan (President & CEO: Hisashi Takahashi, "CAC EXICARE") are pleased to announce today that the companies have launched "CDISC Standard Datasets Creation Support Services" prior to the start of the required electronic study data submission to Pharmaceuticals and Medical Devices Agency (PMDA) in CDISC standard format for new drug application beginning on October 1, 2016.

BDLS and CAC EXICARE started offering "CDISC Standard Datasets Creation Support Services" on November 1, 2015. The services support creating data compliant with CDISC Study Data Tabulation Model (SDTM) for the mandatory submission of clinical study data for new drug application.

The services allow pharmaceutical companies to quickly and easily create high-quality SDTM data compliant with "Notification on Practical Operations of Electronic Study Data Submissions" (April 27, 2015, PFSB/ELD Notification number: 0427-1 issued by Director for Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare) and "Technical Conformance Guide on Electronic Study Data Submissions" (April 27, 2015, PFSB/ELD Notification number: 0427001 issued by Director of the Advanced Review with Electronic Data Promotion Group, Pharmaceuticals and Medical Devices Agency).

Both companies are also moving forward in offering services to support creating data compliant with CDISC Analysis Data Model (ADaM) in the future.

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## **Appendices:**

### **"CDISC Standard Datasets (SDTM and ADaM)"**

- SDTM (Study Data Tabulation Model)
- ADaM (Analysis Data Model)

### **"CDISC Standard Datasets Creation Support Services"**

- The services are based on BDLS's rich experience and technologies for SDTM data creation. BDLS has experience in CDISC data conversion in over 650 studies across over 90 drug submissions to FDA.
- SDTM data is created with a methodology built upon a SAS Data Integration Studio platform which has been developed and tested by BDLS over the last eight years.
- CAC EXICARE validates deliverables from BDLS as well as handling of Japanese data compliant with PMDA regulations.
- The deliverables are provided to Japanese pharmaceutical companies by CAC EXICARE.  
Deliverables: SDTM mapping specification, SDTM datasets, Annotated CRF, SDTM Define-XML, and SDTM Study Data Reviewer's Guide

### **About CAC EXICARE Corporation**

CAC EXICARE is a solutions provider that supports pharmaceutical companies in both contract services and IT systems solutions. From drug discovery and non-clinical activities to post-marketing surveillance, we strongly support all the various processes of the pharmaceutical industry with the best use of IT.

We meet the client needs for supports on global business by various activities with our overseas offices. Alliances with domestic and overseas CRO and SMO as well as IT & BPO vendors lead to a strong synergetic effect to respond quickly and flexibly to meet client needs. We therefore hope to be an essential partner for global business expansion of pharmaceutical companies.

CAC EXICARE Website: <http://www.exicare.com>

### **About Business & Decision Life Sciences**

Business & Decision Life Sciences is part of the Business & Decision Group, an international consulting and Systems Integration company founded in 1992 and listed on the Eurolist C exchange.

BDLS is specialized in the delivery of services and provision of solutions in the Life Sciences industry. With 20 years of experience, it supports its clients in the pharmaceutical, medical device, biotechnology, food and cosmetics industries.

Core skills include the provision of a range of expert CRO and consulting services (supporting clinical trials in the operational, data management, analytical, outcome research, and document writing area) and the implementation of technology-based, clinical applications and solutions tailored for the Life Sciences industry.

BDLS headquarters are located in Brussels, Belgium and has a strong international presence in five countries in North America and Europe.

For more information, visit <http://www.businessdecision-lifesciences.com>