



Announcement on the release of a new service compliant with CDISC standards

Our company is announcing, per below, the release of a new service for pharmaceutical companies that is compliant with CDISC standards.

The Pharmaceuticals and Medical Devices Agency (PMDA) announced that, from 2016, the submission of clinical trial data in CDISC format will be required for new applications for the approval of new drugs.

The CDISC standards were developed in the United States, however, They have become the de facto global standards for new drug development and are beginning to function as a shared system, regardless of nation or region, for making the distribution of clinical data possible.

With this in mind, our company began preparations in 2012 for the contracting of operations based on CDISC standards, and has made progress in internal operational flows assuming CDISC standards, internal implementation training and the outfitting of basic documentation etc., and the implementation of tools necessary for checking data mapping and results.

The contracting operations we are beginning at this time, based on the CDISC standards, are offered to our clients as consultation based services matching their needs. Please refer to the attached materials for more detailed information.

【 Contact 】

Please contact us regarding the CDISC standards compliant service at:

Sales Department, CRO Business Division (General) Tel. 03-5804-7577