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Regarding EPS' Compatibility with International Clinical Data Standards (CDISC Standards)

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As you all are well aware, at the briefing session of the Pharmaceuticals and Medical Devices Agency (PMDA) held on September 10th, 2013, it was announced that as of 2016 submissions of principle clinical data would be requested in a format conforming to CDISC standards (specifically, SDTM or ADaM formats) for applications for the approval of manufacturing new drugs.

Needless to say, as a change to Japanese regulatory requirements, this has a huge impact. 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.

In Japan, the maintenance of a system for clinical data has been behind that of other regions, however, the mandating of CDISC standards data submission can be seen as a movement toward unilateral improvement toward the international standard. This movement will, without a doubt, contribute to a great improvement in the environment for developing new drugs in Japan, and should expand to the collection of post market data, and can be thought to have the possibility of greatly contributing to the improvement of medical standards though the realization of even more efficient EBM.

Now, the question will arise whether the amount of work required to create CDISC standards compliant data is worth the result. The answer is "Yes." However, this is not just a matter of applying CDISC standards to the data submitted to the agency; it is necessary to "reconstruct the total clinical data treatment process around CDISC standards." Of course, if as has been the case, data created without regard to CDISC standards is changed to CDISC standards data (specifically SDTM) after the fact, then the cost of this additional work is incurred. This cannot be said to be a fundamentally CDISC standards compliant approach. Because CDISC standards are "data standards," if their characteristics are understood when used, quality (traceability) and cost management could both be achieved due to rationalization and communization of data processing.

Our company has been paying attention to this point and, since 2012, has been considering and preparing for CDISC standards. Specifically, we currently boast over 20 personnel who have completed official training, and we have maintained basic documentation etc. for an internal operational flow based on CDISC standards. Further, we have been constantly engaged with regard to tools necessary in data mapping and checking of results.

Until now, our company has been contracted with creating and implementing operational processes in accord with each of our client organizations' goals. From here on, with regard to contracts based on CDISC standards compliance, in addition to the above, we hope to offer a proactive proposal based service incorporating CDISC standards content and centered around data specification.

Our company, based on our experience, possesses knowledge regarding the characteristics of Japanese clinical data. Furthermore, as a Japanese CRO, we are constantly engaged in keeping up with Japanese regulatory agencies' information. In addition to that, we are developing our capability in complying with the international level of the CDISC standards. With regard to CDISC standards compliance, the agency announcement has just occurred and there is sure to be more forthcoming, and we hope to contribute to the day soon to come when clinical data is exported from Japan to the world, asking for our client's help.

Our company provides services in line with clients' goals. For example, we provide service as a CRO, understanding the outline of needs at the application project level including those related to CDISC standards, in which we can act as a proxy for clients, who already possess an internal standard in line with CDISC and hope to outsource a portion of those operations. On the other hand, for those who after engaging in a consultation on CDISC standards application to clinical data processing, and who wish to outsource as a whole depending on the situation, we offer a CDISC standards compliance operation achieving both regulatory compliance and operational efficiency as a completely contractible CRO.

Please look forward to our company's new operational service approach.

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