P06-002

FDA SEND in Non-US Countries

Responses to the Standard for Exchange of Nonclinical Data (SEND) in Non-US Countries

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Introduction

The Standard for the Exchange of Nonclinical Data (SEND), adopted by the US FDA, is part of a set of regulations and guidances requiring the submission of standardized electronic study data for nonclinical and clinical data submissions. Thus, non-US countries must consider and develop approaches to SEND that meet their needs. This poster summarizes the real issues in non-US countries concerning with SEND (Fig. 1), and details a compliance scheme (Fig. 2) illustrating how pharmaceutical companies can complete a large amount of work up to an FDA application with the effective utilization of CROs and solution providers.

Needs for SEND (Table 1)

Compared with other regulations, SEND is unique because pharmaceutical companies can use it for various purposes, which can be broadly divided into five categories.

Table 1 Needs for SEND

When	From whom	Why
Application for FDA (IND, NDA, BLA)	FDA	Requirements of regulatory authorities
Cut time to market	All stakeholders	Increased profit for pharmaceutical companies, faster delivery of new drugs to patients
Data trading in a joint development or licensing-in/licensing-out	Trading partners	Prompt data evaluation enables faster value judgment and increases the added value of data
Preparation for SEND regulations of many countries around the world	Authorities of each country	Future requirements
Establishment of data warehouse	Sponsor companies	Bioinformatics, Rapid access to data

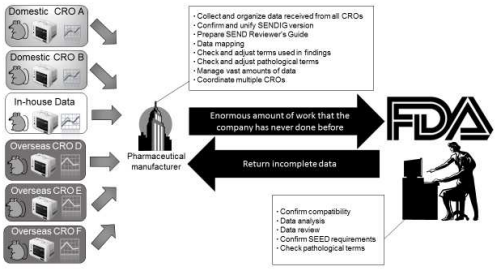

Fig. 1 Current situation of SEND in non-US countries

Challenges in responding to SEND in Japan and other non-US countries and ways to manage them

As Fig. 1 shows, most Japanese pharmaceutical companies often use more than one Japan-based CRO as well as CROs based in Europe and/or the US for the development of one product. This means they need to conform the data created in multiple countries and facilities to the SEND requirements. In these cases, not all the commissioned CROs can necessarily use SEND or use it in a manner that meets the client's needs. Another aspect that needs to be taken into account is the analyses and tests contracted out by CROs to subcontractors.

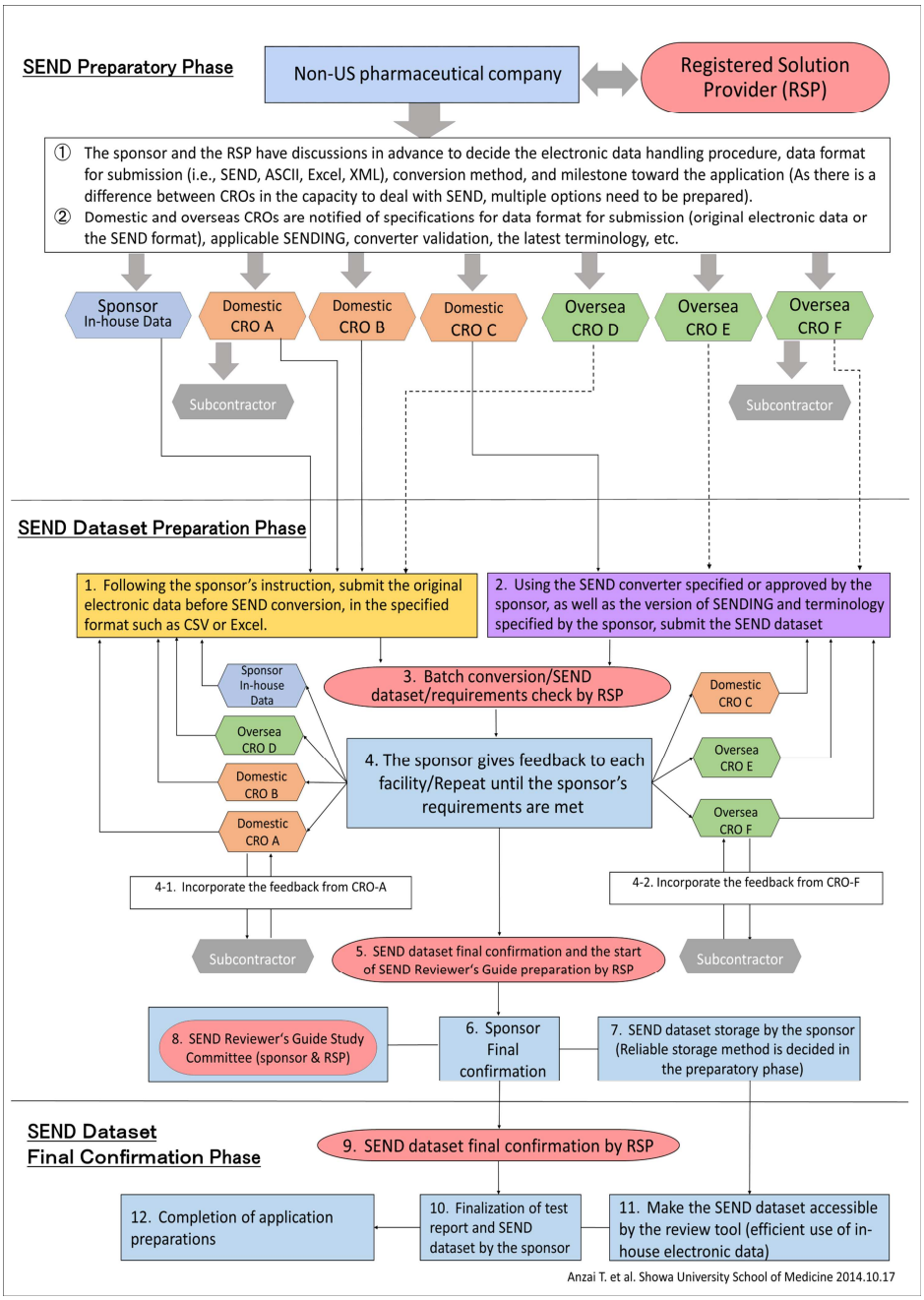

Fig. 2 SEND compliance scheme in Japan and other non-US countries

Efficient ways for Non-US pharmaceutical companies to respond to SEND

Fig. 2 illustrates non-US countries' pharmaceutical companies can overcome challenges by using CDISC Registered Solution Providers (RPSs). One of this scheme's characteristics is that the phases from SEND dataset preparation to final confirmation are described based on the use of CROs with different nationalities and capacities to use SEND.

SEND Preparatory Phase

In the SEND preparatory phase in Fig. 2 (top), the sponsor pharmaceutical company consults with an RSP to summarize the proper requirements while taking into account each CRO's capacity to comply with SEND (Fig. 2, SEND Preparatory Phase ① and ②).

SEND Dataset Preparation Phase

The SEND dataset preparation phase in Fig. 2 (middle) starts with classification of the data, which were received from CROs into two forms according to their response ability to SEND capacities (Steps 1 and 2). Steps 2 and 3, Steps 1,3 and 4, or Steps 2-4 are repeated until the sponsor's requirements are met.

SEND Dataset Final Confirmation Phase

The SEND dataset final confirmation phase in Fig. 2 (bottom) is an important phase in which the sponsor verifies the compatibility of the SEND dataset with the FDA's screening system. The RSP or sponsor submits the SEND dataset before finalization to FDA for a trail submission, in which the FDA's validation tools are used to verify that no compliance errors are found in the dataset that will interfere with processing and analyzing the electronic data (Step 9).

Storage and browsing of the SEND dataset

The dataset before finalization, which was stored in the SEND dataset final confirmation phase in Fig. 2 (Step 7), or the finalized dataset needs to always be accessible by the sponsor or RSP with the dataset review tool (Step 11).

Conclusion

The largest risk associated with SEND is that of a refusal to file from FDA. FDA clearly states that it will return the SEND dataset to the applicant if FDA's validation system identifies errors. Even if an application with a SEND dataset is returned for reexamination, CROs and vendors will not be held responsible. It is obviously the applicant pharmaceutical company that takes on the responsibility and associated risks. The largest challenge related to SEND is how pharmaceutical companies can avoid these risks in an adequate manner. Therefore, we think the compliance scheme (Fig. 2) explained in this scheme is a very practical way to deal with SEND in Japan or other non-US countries.