

## 医薬品の安全性評価の効率化に向けた Standards for Exchange of Nonclinical Data (SEND) に基づく非臨床電子データの活用に関する基本的検討

笛木 修<sup>\*1, #</sup>, 松本 峰男<sup>\*1</sup>, 角田 聡<sup>\*1</sup>, 星野 裕紀子<sup>\*1</sup>, 大瀧 清<sup>\*2, \*3</sup>,  
鈴木 睦<sup>\*2, \*4</sup>, 佐藤 玄<sup>\*2, \*5</sup>, 木ノ本 寿子<sup>\*2, \*6</sup>, 中村 和希<sup>\*7</sup>, 中江 大<sup>\*8</sup>,  
高橋 祐次<sup>\*9</sup>, 平林 容子<sup>\*9</sup>, 西川 秋佳<sup>\*9</sup>

(受付：平成30年8月16日，受理：平成30年11月16日)

Basic Consideration on the Application of Standards for Exchange of Nonclinical Data (SEND) —Based Electronic Non-clinical Data to Improve the Efficiency of the Safety Assessment of Pharmaceuticals

Osamu FUEKI<sup>\*1, #</sup>, Mineo MATSUMOTO<sup>\*1</sup>, Satoshi TSUNODA<sup>\*1</sup>, Yukiko HOSHINO<sup>\*1</sup>,  
Kiyoshi OHTAKI<sup>\*2, \*3</sup>, Mutsumi SUZUKI<sup>\*2, \*4</sup>, Gen SATO<sup>\*2, \*5</sup>, Toshiko KINOMOTO<sup>\*2, \*6</sup>,  
Kazuichi NAKAMURA<sup>\*7</sup>, Dai NAKAE<sup>\*8</sup>, Yuhji TAQUAHASHI<sup>\*9</sup>, Yoko HIRABAYASHI<sup>\*9</sup>  
and Akiyoshi NISHIKAWA<sup>\*9</sup>

### Summary

In FY2017, a subgroup consisting of the authors of this paper, and belonging to the national research group for the international harmonization of regulations to ensure the safety and quality of pharmaceuticals, funded by the Japan Agency for Medical Research and Development (AMED), has carried out an investigation on the application of Standards for Exchange of Nonclinical Data (SEND)-based electronic non-clinical data. We examined the possibility of applying SEND data in the new drug application (NDA) review system, in Japanese regulation for pharmaceuticals, and also considered how SEND data should be used in drug safety evaluation in general. As a result, a basic policy regarding the evaluation of drug safety using SEND data has been drawn up, and issues to be considered have been identified. These include 1) standardization of terminology in toxicity studies, 2) guaranteeing the reliability of SEND datasets, and 3) ensuring the consistency of the systems for using SEND data among regulatory agencies. The examination continues, and as a part of the work, we will investigate analytical methods for drug safety evaluation using actual SEND data ("SEND Trial").

### Key words

SEND, CDISC, Nonclinical data, Electronic submission, Safety assessment, FDA, PMDA