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Letter from Editor

Dear TBI readers,



Although we are living in one of the most technologically advanced periods in history, we are reminded daily about the major challenges facing drug development such as the standardization of drug clinical R&D, the safety of drug development and understanding of complicated regulatory affairs.

Over this last year, resolutions on how cardia safety of a new drug should be monitored during its clinical studies were published by International Conference on

Harmonization (ICH). Meanwhile US FDA, while celebrating its 100 anniversary, also published several new guidelines regarding the drug safety surveillance. These new guidelines are their response to public and congressional criticisms subsequent to the NSAID and antidepressant controversies. With these changes in places, “real time information” from drug industries may be used to identify surrogate endpoints and to better predict product safety.

Additional good news on the horizon is that the development of universal standards for clinical trials is getting its momentum with the establishment of CDISC (Clinical Data Interchange Standards Consortium) after 8-year comprehension. CDISC is assuming a key position in a process that will be helpful to develop and support global, platform-independent data standards to improve medical research and related areas of healthcare. In this issue, author provided extensive reviews from different angles.

While providing pioneer overviews on these issues, we encourage you to afford your opinions, comments and letters to us. Without your participation and contribution, the goal to make the Journal being the top of critical and initiative opinions would never come true. All responses can be sent to tbi@sapa-west.org.

Enjoy your reading!

Daniel Liu
Editor