Drug safety evaluation is an important issue throughout the lifecycle of drug product development, and real-world evidence plays an essential role. Randomized controlled trials are considered to provide the highest level of scientific evidence for clinical therapies. However, inappropriate usage of medications, and long-term and rare adverse effects are not easily evaluated in traditional clinical trials. Therefore, clinicians must evaluate the benefits and risks and make decisions regarding therapies from various sources. In general, using real-world data with appropriate study designs, suitable epidemiological methods and well-controlled bias and confounding effects, real-world evidence can be generated. Such evidence can also bridge the gap from randomized controlled trials to demonstrate the efficacy and safety of medications or medical products in the real world.

Authors are invited to submit original and review articles on drug safety, therapeutic effectiveness and the economic burden of all common therapies which can be published in the Special Issue ‘Drug Safety and Effectiveness in the Real World’ of **Pharmacoepidemiology**.