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The challenge in the design and operation of late phase clinical trials

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Phase III and Phase IV studies have been performed as one of regulation's requirement often. More safeties and more efficacies could be kept by clinical studies after FDA's approval. The phase III clinical trials include big number of subjects and need high cost in comparison to phase I and phase II. In addition, they must meet need of ethics completely too. The value of phase IV studies has been emphasized in terms of keeping safety and efficacy post approval. There are more types of studies in late clinical studies, including observational studies, post marketing surveillance as well as phase IV trials/studies. There are challenges of designing the late studies and operation of them in the practice. The practical challenges are introduced and the solutions which would be practiced to keep the studies from damage in the field are shared.

Biography

Seung Eun Choi has completed her MD from College of Medicine, Seoul National University, and Surgery Residency from Seoul National University Hospital. She completed her Clinical Fellowship in Pediatric Surgery in Seoul National University Children Hospital. She has completed her PhD in Transplant Immunology as full-time Researcher from Microbiology and Immunology Department in College of Medicine, Seoul National University. Previously, she did *in-vivo* experiment in immunology area during 6 years and has worked in several healthcare companies.

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