

First-in-Human (FIH) to Proof-of-Concept (PoC) studies in Japan for early access of pharmaceuticals for patients around the world, even at an international pharmaceutical company

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At international pharmaceutical companies and even at some Japanese pharmaceutical companies, FIH to PoC studies are usually conducted outside Japan. However, there are many professional clinical pharmacology (CP) sites in Japan that can conduct FIH studies meticulously, resulting in lower variability of data and decreased noise. This is advantageous to see signals of biomarkers in a relatively small study. A common misunderstanding is that Japan is slow and expensive to conduct clinical studies. This is not true. The regulatory timeline of Japan's first Clinical Trial Notification (CTN) is 30 days, which is the same as opening an Investigational New Drug (IND) in USA. Recent examples showed that Japan CP sites are less expensive than sites in USA. So why are FIH and PoC studies not conducted in Japan? It is because people outside Japan do not realize that there are great CP and PoC sites in Japan, and do not trust the Japan affiliate to conduct these studies. Since I moved to Novartis, I have been leading the Translational Medicine Japan department, which includes pharmacology, toxicology, pharmacokinetics (PK) and operations from Phase 1 to PoC. For early access to pharmaceuticals for patients around the world, we would like to conduct FIH to PoC studies in Japan, even at an international pharmaceutical company.