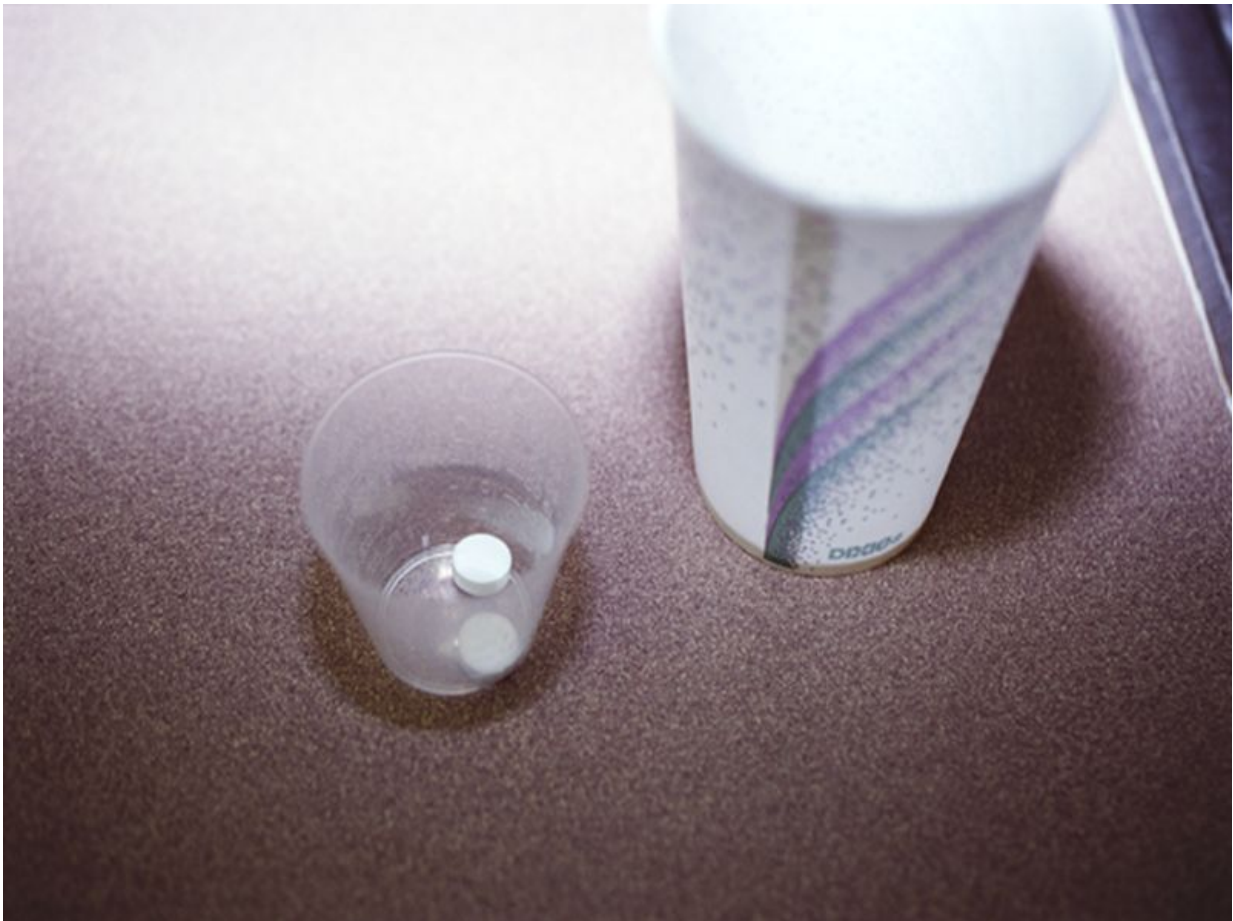


Strategies compared for cancer medication submission lags

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(HealthDay)—For development of oncology drugs in Japan, the global

trial (GT) strategy and early-initiation bridging (BG) strategy are associated with shorter submission lag (SL) than late-initiation BG strategy, according to a study published online June 19 in the *Journal of Clinical Pharmacology*.

Seiji Kogure, from Nihon University in Funabashi, Japan, and colleagues examined the potential factors that impact SL and compared the differences in SL among the early- and late-initiation BG strategies, and the GT strategy for [oncology drugs](#).

The researchers note that development start lag and development style potentially shorten SL. SL was found to be significantly shorter in the GT strategy and the early-initiation BG strategy compared with the late-initiation BG strategy.

"The findings in our study suggest that the late-initiation BG strategy may not contribute to shortening [drug lag](#)," the authors write. "Because the number of late-initiation BG studies has not decreased, we propose first that pharmaceutical companies should initiate clinical [development](#) as early as possible in Japan so that they can choose the GT strategy as a first option at the next step, and second when they cannot choose the GT strategy after investigating differences in exposure between Japanese and non-Japanese in a phase 1 study, they should select the early BG strategy to avoid future drug lag."

Two authors are employees of Daiichi Sankyo Co.

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