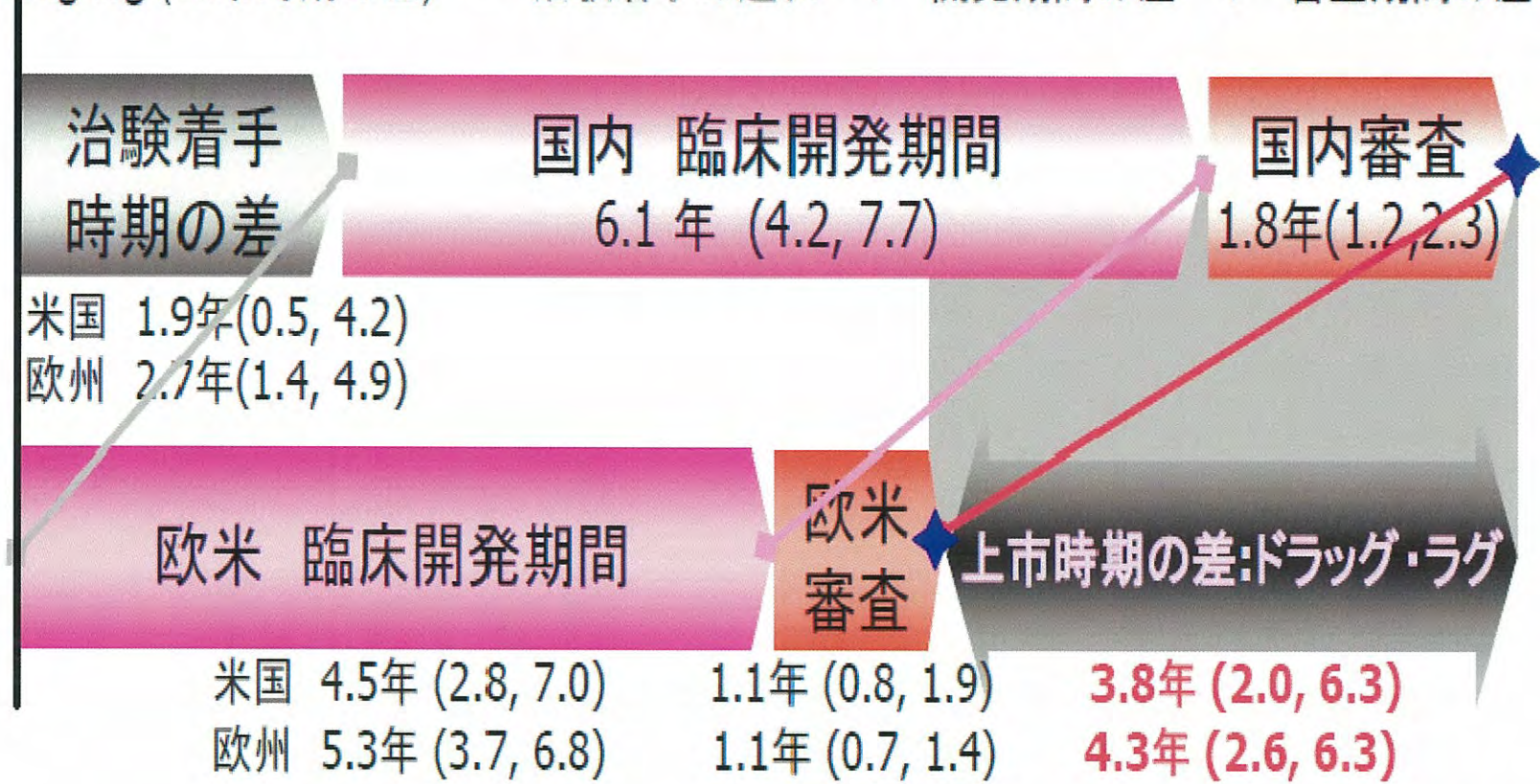


Drug lag (上市時期の差) = 治験着手の遅れ + 開発期間の差 + 審査期間の差



n=54 中央値 (25パーセンタイル,75パーセンタイル)

➡ **日本国内の新薬の市販が欧米から約4年遅れている**

政策研ニュース No 24 (2008年2月): <http://www.jpma.or.jp/opir/news/news-24.pdf>

Department of Health and Human Services
**OFFICE OF
INSPECTOR GENERAL**

**CHALLENGES TO FDA'S ABILITY TO
MONITOR AND INSPECT FOREIGN
CLINICAL TRIALS**

FDA inspected clinical investigators at less than 1 percent of foreign sites. FDA inspected clinical investigators at only 1.2 percent of clinical trial sites for applications approved in FY 2008. FDA inspected 1.9 percent of domestic clinical trial sites and 0.7 percent of foreign clinical trial sites. The agency targeted domestic sites and original



Daniel R. Levinson
Inspector General

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