



Comparison of FDA and EMA Review of Oncology Drugs (2004-2016)

Summary of Original Findings from 2011 *Health Affairs* article:¹

Between 2003 and 2010, **23** oncology drugs were approved by **both** the FDA and EMA. For these 23 drugs:

- The median review time for FDA was 182 days
- The median review time for EMA was 350 days
- All (100%) of the drugs that were approved by both regulatory agencies entered the US market prior to the EU market

Drugs Approved by Both FDA and EMA (2003-2010)		
n=23		
	FDA	EMA
Median Review Time (in days) ²	182	350
# Drugs reviewed w/in 6 months	15 (65%)	1 (4%)
# Drugs reviewed w/in 1 year	22 (96%)	17 (74%)

Summary of Updated Findings:

Between the years 2003 and 2016, **73** oncology drugs were approved by **both** the FDA and EMA. For these 73 drugs:

- The median review time for FDA was 183 days
- The median review time for EMA was 356 days
- Seventy-one (97%) of the 73 drugs approved by both agencies entered the US market prior to the EU market

Drugs Approved by Both FDA and EMA (2003-2016)		
n=73		
	FDA	EMA
Median Review Time (in days)	183	356
# Drugs reviewed w/in 6 months	36 (49%)	1 (1%)
# Drugs reviewed w/in 1 year	70 (96%)	45 (62%)

¹ Original Results from 2011 *Health Affairs* article available at: <http://content.healthaffairs.org/content/30/7/1375.full>

² Review times calculated as follows: 1) For FDA, the time between submission of a New Drug Application (NDA) and sponsor receipt of approval letter from FDA; 2) for EMA, the time between submission of marketing application and Committee for Medicinal Products for Human Use (CHMP) positive opinion date.