Last Updated: 12/31/16

**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.