Oncology drugs get faster approvals than non-oncology drugs in U.S.

But in the EU, non-oncology drugs get faster approval than oncology drugs

- Total development and approval time for NME and new BLA oncology and non-oncology approvals in the U.S. was 8 years in 2002-06 and 7.4 years in 2007-11.
- During 2007-11, FDA approval times for oncology drugs were 10 months shorter than EMA approval times.
- Total development and approval time in the U.S. for fast track drugs during the 2000s dropped by 20% – from 8.3 years in 2002-06 to 6.6 years in 2007-11.
- Orphan designations for U.S. oncology drugs rose during the 2000s; other designations fell.
- U.S. oncology drug approval times were half those of Europe during 2007-11, regardless of designation status.

Over the past 20 years, the United States Food and Drug Administration (FDA) and the European Union’s European Medicines Agency (EMA) have implemented programs to streamline the development and approval process for certain therapeutics. At the FDA, these programs include the Orphan Product and Fast Track designations, and Accelerated Approval, targeting therapies for rare diseases, unmet medical needs, and life-threatening diseases. The EMA also utilizes orphan designations, approval under “exceptional circumstances,” in rare cases where comprehensive evidence cannot be provided, and, more recently, conditional marketing authorization when the necessary data for full approval are expected to be provided within an agreed timeframe in the near future. In both regions, oncology products benefit from these programs.

A recent Tufts CSDD analysis of new oncology product approvals in the U.S. and the EU found that approval times for oncology products in the U.S. were shorter than approval times for non-oncology products, while approval times in the EU were shorter for non-oncology products. Moreover, while oncology products received a greater share of all special program designations in the U.S., in both regions there was little difference in the approval times between products that had a special designation and those that did not. These and other results from the analysis are highlighted in this Tufts CSDD Impact Report.