Cardiovascular drug approval rate in the U.S. fell as development time rose

But development time was less for cardiovascular vs. other drugs during 1999-16

- The overall clinical approval success rate for cardiovascular drugs first tested in human subjects from 1995 to 2007 was 3.7%, or less than one-third the 12.9% rate for non-cardiovascular drugs.
- Approval success rates for cardiovascular compounds first tested in human subjects in 2001-07 fell by 58% compared to those first tested in 1995-00 – from 5.2% in the earlier period to 2.2% in the later period.
- Fewer new cardiovascular drugs received a priority rating compared to other drugs approved during 1999-16 (38% vs. 50%).
- Clinical development time was 14% shorter and regulatory approval time was 22% longer for cardiovascular vs. non-cardiovascular drugs approved during 1999-16.
- The cardiovascular share of new drug approvals in the U.S. declined from 27% during the 1980s to 13% during 2011-16.

While heart disease has been the leading cause of death for decades in the United States, the relative share of new cardiovascular drugs receiving marketing approval from the Food and Drug Administration (FDA) declined by 52% from the 1980s through 2016. Although clinical development time for cardiovascular drugs that received FDA approval increased by 47% from 1999 through 2016, cardiovascular drugs have shorter clinical development times, on average, compared to all other approved drugs, six vs. seven years.

The development gauntlet seems especially challenging for cardiovascular drugs, and has been exacerbated by, among other factors, rising costs and regulatory uncertainty. The net result is that only 2% of cardiovascular compounds that entered clinical testing in the 2001-07 period eventually obtained marketing approval – approximately one-sixth the rate for non-cardiovascular compounds. At the same time, investment in other therapeutic areas has been growing. The demand for new cardiovascular products is likely to continue, especially as heart disease is projected to continue to account for about 25% of all U.S. deaths. The question for developers is how well they can surmount the obstacles along the way to approval.