While total approvals decline, U.S. is preferred market for first launch

U.S. drug approvals dropped to 48 in 2005-07 from peak of 110 in 1996-98

- U.S. approval of new drugs has steadily declined from its peak in the 1996-98 period.
- The number of U.S. approvals marketed first in the U.S. continues to climb, and reached an all time high of 75% in 2005-07, from a low of 20% in 1987-89.
- Combined clinical and approval times have dropped to the lowest level since the late 1990s.
- Following a jump in clinical times for priority and standard drugs in 2002-04, those numbers in 2005-07 returned to levels similar to those observed in 1996-98 and 1999-01.
- Average total time from IND filing to NDA approval for drugs approved in 2005-07 was longest for endocrine drugs—8.9 years—and shortest for antineoplastic drugs—6.1 years.

Drug developers are making headway in their efforts to reduce the time needed to bring new prescription medicines to market. Average total clinical and approval times have dropped to 7.2 years in recent years, down from a high of 9.4 years in 1990-92. This decline results, in part, from the industry's efforts to boost the efficiency of clinical operations, better project management and portfolio decision making, and the relatively high percentage of priority drugs relative to total approvals in 2005-07.

Not to be overlooked is the impact of the Prescription Drug User Fee Act of 1992 [PDUFA], re-enacted three times since, the goal of which is to speed patient access to safe and effective new medicines. It seems to be achieving its intended purpose. The major takeaway for developers is to keep up the momentum: continue to find more ways to accomplish more with less resources in less time. This Tufts CSDD Impact Report updates a continuing series of three-year Tufts CSDD analyses of drug development trends. See also Tufts CSDD Impact Report 2005 Nov/Dec;7(6) and Tufts CSDD Impact Report 2002 Nov/Dec;4(6).