Fast track designations more than doubled during the last five years

Since it was authorized in 1997, the U.S. Food and Drug Administration’s (FDA) fast track program—designed to expedite the study and approval of new medicinal products to treat serious or life-threatening conditions—has given millions of patients in the U.S. access to drugs that treat diseases such as AIDS, breast cancer, and leukemia. A recent Tufts CSDD analysis, summarized in this report, shows that the fast track program has evolved over the past decade, and that there were notable differences between fast track candidates designated during 1998-02 and those designated during 2003-07. However, because most of the 2003-07 designated candidates are still in clinical studies, trends for this cohort will not be evident for some time.

Determining the value of the fast track program requires care, as traditional metrics may not fully capture that value. For example, close and early communication, during the development phase, between sponsors, especially small- to medium-sized companies, and the FDA, provides an immeasurable benefit to the firms. Tufts CSDD will continue to assess the program’s impact on the nature and pace of development of critical new medicines. [See back page for references to earlier Tufts CSDD analyses.]