Monoclonal antibody products—known as mAbs—are big business: in 2006, the global market for these products exceeded $17 billion, with sales forecasted to grow an average of 14% per year through 2012. Historically the province of biotechnology companies, mAbs are now just as likely to be developed and marketed by major pharmaceutical firms. Currently, 21 such products have been approved for sale in the United States and abroad, and more than 200 are in clinical study.

Strong and growing interest in mAbs means that all interested parties, including developers, regulators, and investors, need a better understanding of key metrics, such as numbers of products entering clinical study, sources of mAb sequences, approval success rates, and clinical phase transition probabilities. The Tufts Center for the Study of Drug Development, building on previous analyses of clinical development and approval trends involving therapeutic mAbs, recently completed a study of mAbs in development. The results are summarized in this Tufts CSDD Impact Report.