



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Therapeutic peptides in clinical study in 2000-07 nearly doubled 1990s rate

Approval success rates have remained steady – in the 21%-24% range

- Of 318 therapeutic peptides included in the analysis, 42% are currently in clinical development, with the remainder either in regulatory review, approved in at least one country, or terminated.
- 68% of products that entered clinical study during 2000-07 are in Phase I or Phase II studies.
- The average annual number of therapeutic peptides entering clinical study in the 2000-07 period nearly doubled, to 16.9 from 9.7 during the 1990s.
- During 2000-07, new peptides entering clinical development were most frequently studied as treatments for metabolic (26%) indications, one of 15 therapeutic areas in which peptides were being developed.
- Average total clinical study and FDA approval time for new therapeutic peptides was 10.8 years.
- Efficacy issues and commercial considerations were most often cited as reasons for discontinuing clinical studies of new therapeutic peptides.