



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Rising protocol complexity, execution burden varies widely by phase and TA

New study updates Tufts CSDD assessment of impacts of protocol design

- The median number of procedures per clinical trial increased by 49% between 2000-03 and 2004-07, while the total execution burden grew by 54%.
- Wide variability exists in complexity and execution burden per protocol between therapeutic areas (TAs) and phases, indicating targeted opportunities to streamline design.
- Between 2002 and 2007, protocols targeting diseases in oncology, immunology, and central nervous system (CNS) saw the most rapid growth in the total number of procedures and in the burden to execute those procedures.
- During that period, Phase II and Phase IV studies experienced the greatest relative growth in complexity and execution burden.
- Overall growth in complexity and execution burden grew at the slowest rate for protocols in Phase III, as companies, looking to contain costs, gathered more data in early phases of clinical research.