Volume 14, Number 6 • November/December 2012

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

One in five procedures generates extraneous clinical trials data

Tufts CSDD study sets benchmark for quantity and cost of less essential data

- The typical protocol has an average of 7 objectives and 13 endpoints.
- 22.3% of all procedures are considered to be non-core: 17.7% of Phase II procedures and 24.7% of Phase III procedures.
- Half of all procedures—54.3% of Phase II procedures and 47.9% of Phase III—support primary and key secondary endpoints.
- $1.1 million (18%) of a typical study budget is spent on procedures for supplementary secondary, tertiary, and exploratory endpoints, and another $1.3 million (22%) is spent on procedures supporting regulatory compliance.
- Based on the total number of active FDA-regulated Phase II and III trials conducted annually, the pharmaceutical industry spends $4 billion to $6 billion each year on procedures that generate extraneous clinical trial data.