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, gathering more data in early phases of clinical research.

Research conducted by Tufts CSDD in 2007 demonstrated the dramatic impact that protocol design strategies and practices have had on extending study cycle times, raising study budgets, and challenging investigative site and study volunteer participation. A growing number of pharmaceutical and biotechnology companies now recognize the critical need to stem the rise in protocol complexity, to achieve a sustained improvement in operating performance.

Based on feedback from sponsor companies interested in targeting specific areas to improve the protocol design process (e.g., overall process redesign, authoring, feasibility assessment, template redesign), Tufts CSDD conducted a follow-up study in 2009, which examined protocol complexity by phase and therapeutic area. This Tufts CSDD Impact Report provides a summary of that study's findings.