

BACKGROUND

Inconsistencies between collected data and study endpoints drive inefficiencies in Investigator Initiated Trials (IITs), increasing workload, extending analysis timelines and reducing data utility. A 2024 Tufts Center for the Study of Drug Development (Tufts CSDD) analysis with 15 TransCelerate BioPharma companies, reported that up to 40% of data collected in academic trials are not linked to primary or secondary endpoints. Additional evidence shows that 25% of phase III and 18% of phase II trial data support supplementary or exploratory endpoints, rather than endpoints for safety. To support data-driven, endpoint-focused trial design, we evaluated endpoint alignment across selected UF Health Cancer Institute (UFHCC) IITs and developed a standardized assessment tool.

GOALS

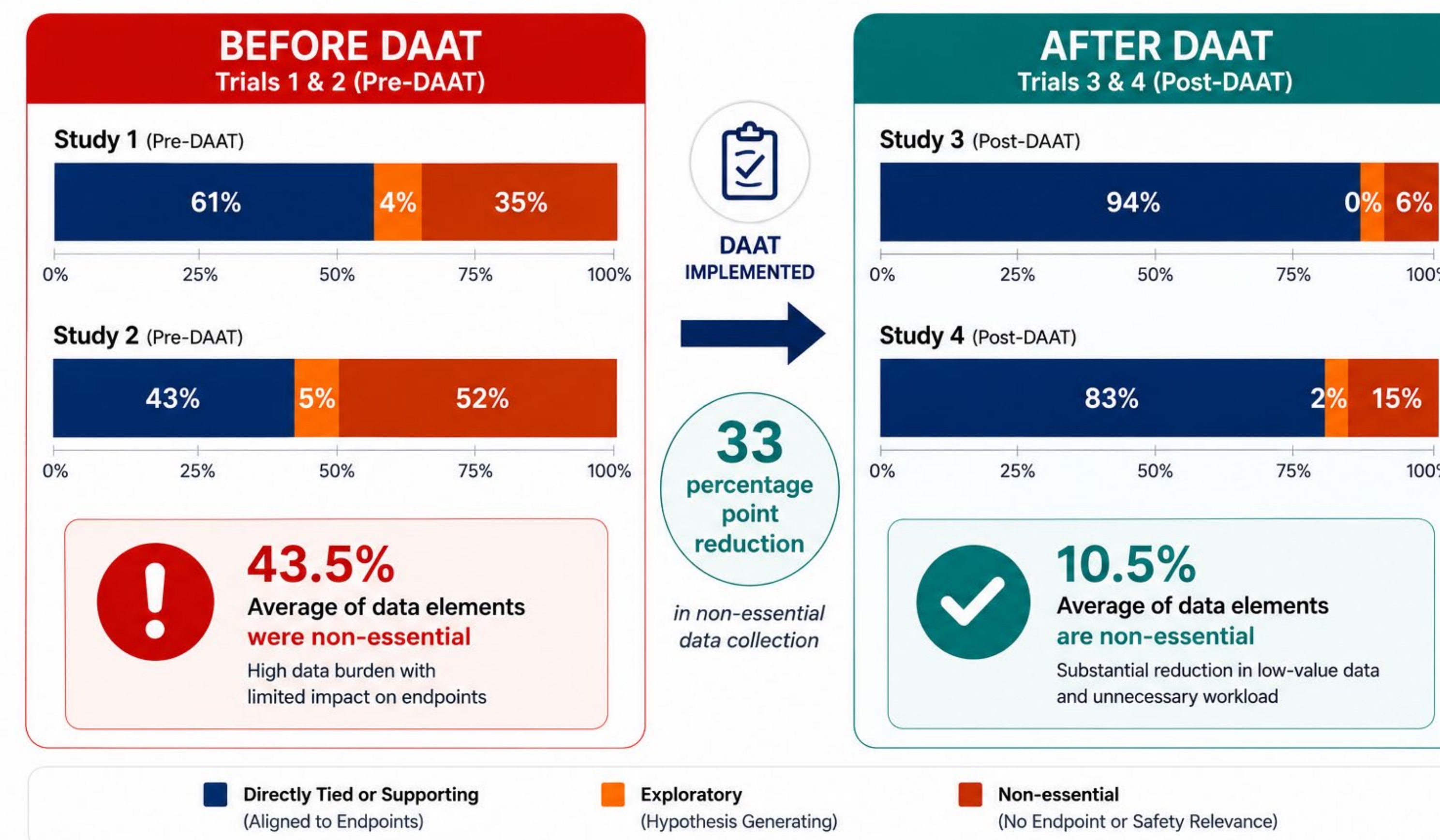
- ❖ Assess proportion of data elements aligned to study endpoints.
- ❖ Develop a standardized Data Alignment Assessment Tool (DAAT) for use during protocol development.
- ❖ Pilot DAAT to identify opportunities to streamline data collection and enhance endpoint relevance.

OUTCOMES

A 33-percentage point reduction in non-essential data points was observed in post-DAAT implemented studies (average of 43.5% non-essential data points in pre-DAAT trials, compared to 10.5% in post-DAAT trials). Commensurately, directly tied or supporting data point percentage improved by 36.5 percentage points (average 52% directly tied or supporting data points for pre-DAAT trials, and average 88.5% in post-DAAT trials.)

DAAT Reduced Non-essential Data Collection by 33 Percentage Points

Improving alignment with study endpoints and reducing data burden



Pilot implementation demonstrated that it is feasible to identify non-essential data elements early in protocol development, resulting in measurable reductions in non-essential data collection while maintaining endpoint integrity and regulatory compliance.

LESSONS LEARNED AND FUTURE DIRECTIONS

Many IITs collect exploratory and non-essential data that increase workload without clear benefit. Findings highlight importance of early, endpoint-based data mapping to promote clarity, efficiency, and regulatory alignment. The DAAT is a practical, scalable approach for improving data relevance and supporting endpoint-focused trial design, with future efforts focusing on institutional adoption to further assess feasibility, impact on data volume and effectiveness, with and overarching goals of improving data quality, reduction of staff workload, and enhanced feasibility and efficiency of IITs.

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