TransCelerate and Tufts CSDD Uncover Opportunities to Rethink Data Collection and Optimize Protocol Design

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Optimizing Data Collection: TransCelerate Initiative

Objective: Identify key considerations in protocol design to optimize procedures and their frequency, while providing tools and a value-based framework for internal evaluation

Why Now

Rising Data: Data volume keeps rising, often beyond what's needed.

Regulatory Momentum: ICH guidances emphasize the importance of measured, risk-proportionate data collection.

Better for all: Less non-essential data = lower patient/site burden, clearer reviews.

What ODC Can Enable

Improve patient and site experience by reducing burden and unnecessary complexity

Reduce complexity of data collection

Enhance trial execution through **better design decisions**

Maintain (or potentially improve) quality

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Visit our website to view the full Regulatory Landscape Assessment!

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Regulatory Momentum: Collect Only What Matters

ICH guidances emphasize the importance of measured, risk-proportionate data collection

Why Now:

1. **Clear direction:** Recent ICH and ethics updates emphasize fit-for-purpose data and eliminating unnecessary complexity in clinical trials.
2. **Shared upside:** Removing non-essential data fields reduces site workload, accelerates study submissions, and eases the burden on patients. Regulators benefit from cleaner, more focused datasets.
3. **Lag costs:** Collecting more may lead to longer builds, increased monitoring spend, and more challenging inspections.

Guideline	Date
E6(R3) Good Clinical Practice	Jan 2025
E8(R1) General Considerations for Clinical Studies	Oct 2021
E9(R1) Estimands and Sensitivity Analysis	Feb 2020
E19 Selective Safety Data Collection CDER C3TI Topic	Dec 2022
E20 Adaptive Clinical Trials CDER C3TI Topic	Jun 2025
M11 Clinical Protocol Template	Mar 2025
Declaration of Helsinki	Oct 2024

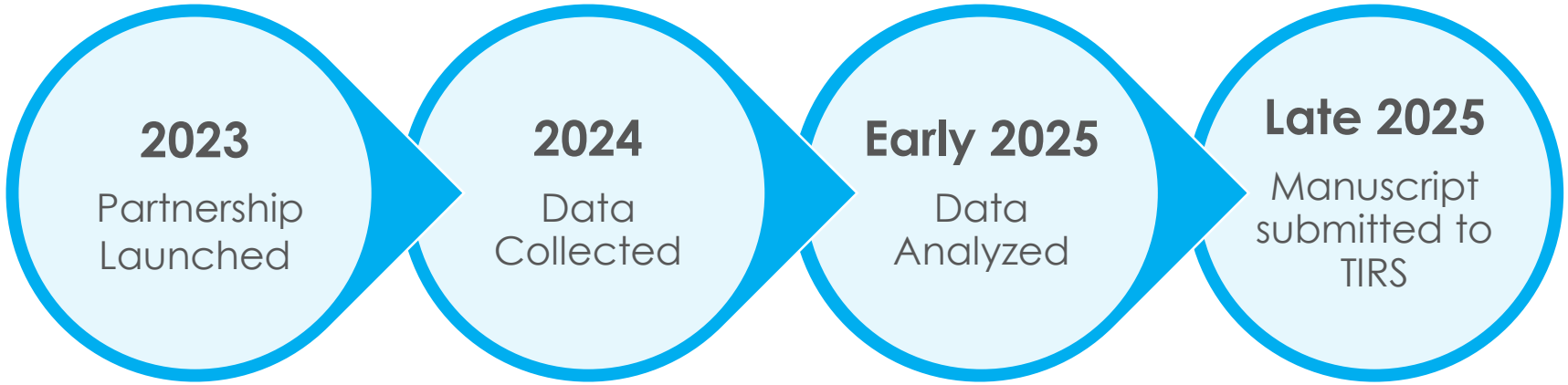
*ICH "E" guidances should be viewed as a **unified framework**.*
*Their concepts are interdependent and require a **team effort across functions** to implement effectively.*

Collaborative Study: TransCelerate – Tufts Center for Study of Drug Development (CSDD) Partnership

The need for continued **tangible, actionable evidence** to demonstrate there is an opportunity to optimize data collection.

Study Objectives

- **Quantify** the collection and use of non-core and extraneous core protocol data
- **Gather updated benchmarks** on the amount, purpose, and impact of data collected in clinical trials, building on earlier CSDD research
- **Find ways to improve protocol design** by reducing complexity and easing the burden on sites and participants



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Methods and Data Characteristics

- The **data collection instrument** was workshopped throughout Spring 2024; A **data warm-up exercise** was conducted between June and July 2024
- **14 Companies** collected and provided their own data between July and November 2024
- Tufts CSDD conducted **data quality checks** to ensure accuracy, validity and completeness and conducted a comprehensive QC process
- Database locked and analysis initiated at the end of January 2025
- **105 Total protocols**
  - 41% phase II; 59% phase III
  - 63% small molecules
  - 26% oncology, 16% endocrinology, 13% immunology, 11% infectious diseases, 9% neurology

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Definitions: Procedure Types by Endpoint Category

CORE

- Procedures supporting primary and/or secondary objectives
- Procedures supporting primary, *key* secondary and safety endpoints

NON-CORE

- Procedures supporting tertiary and exploratory objectives and endpoints
- Procedures supporting supplementary secondary endpoints
- Safety and efficacy procedures that are not included as an endpoint or objective
- Procedures not tied to endpoint or objective

REQUIRED (Regulatory Compliance)

- Screening requirements
- Informed Consent
- Drug dispensing (compliance)

STANDARD

- Routine procedures including gathering data on baseline health, concomitant medications, demographics, adverse event and adverse drug reactions

Source: Tufts CSDD

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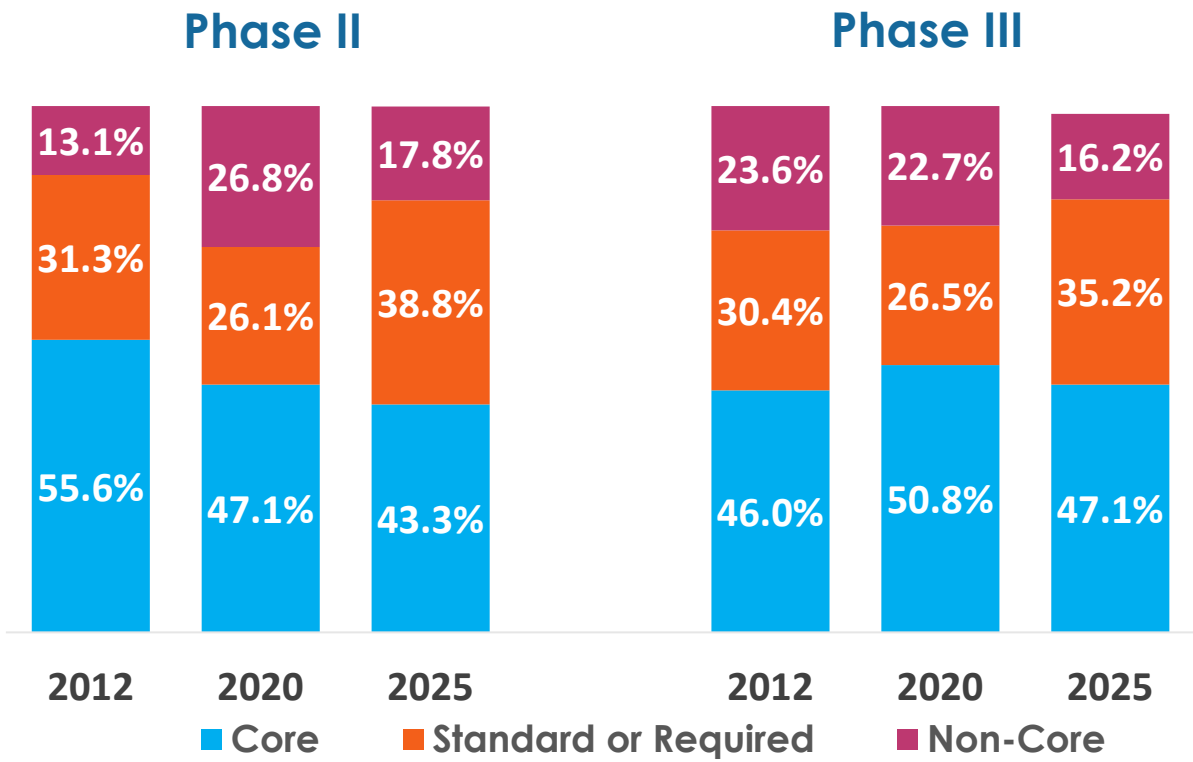
Procedure Types and the Endpoints They Support

Distribution of Procedures By Endpoint Category

Endpoint Category	Phase II	Phase III
Core	43.3%	47.1%
Standard or Required	38.8%	35.2%
Non-Core	17.8%	16.2%

**Mean Percentages*

Trends in Procedure Type by Endpoint Category



Source: Tufts CSDD, 2025

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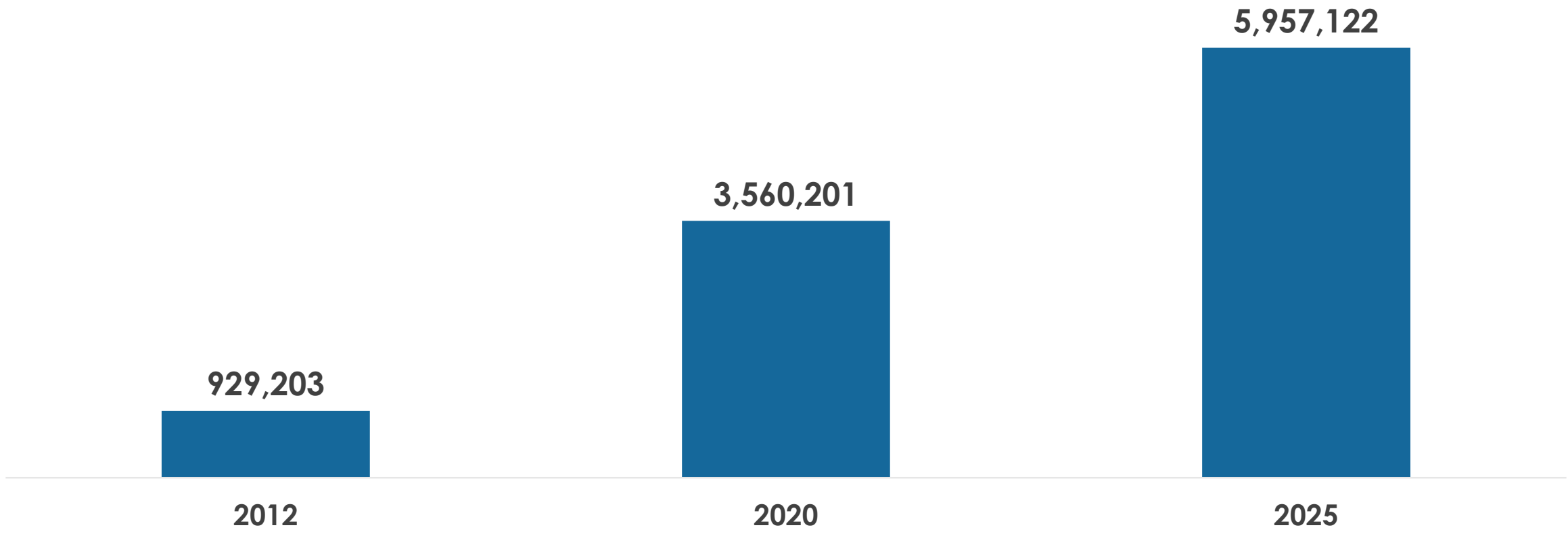
Total Data Volume in Phase III Clinical Trials

Mean total number of datapoints collected



Source: Tufts CSDD, 2025

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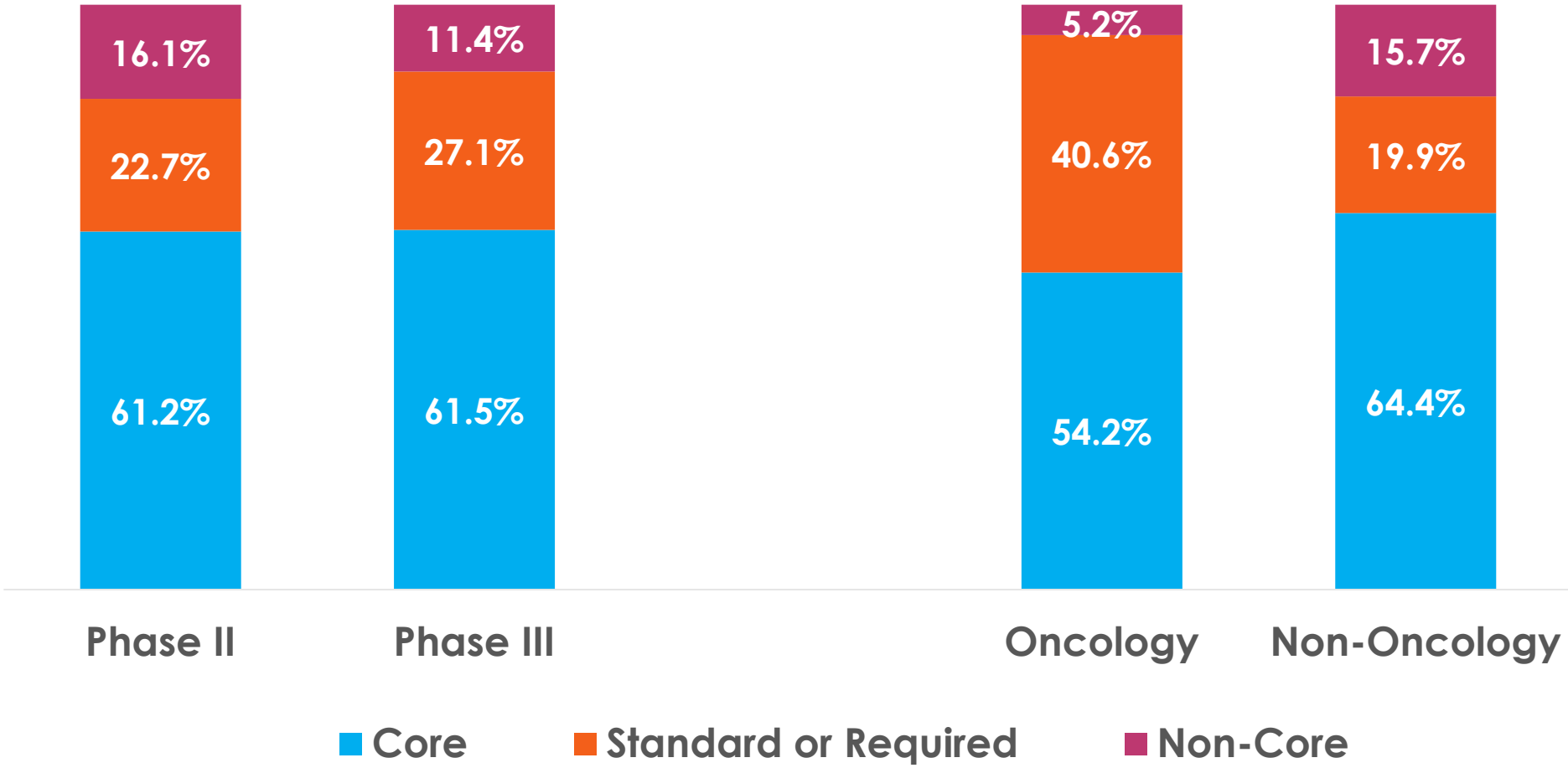
Distribution of Datapoints Collected per Participant



Source: Tufts CSDD, 2025

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Procedural Contribution of Datapoints that are Non-Core

Combined Phase II - III Clinical Trials	Mean Percentage
Patient Diaries	37.5%
Questionnaires	37.1%
Invasive Procedures	25.9%
Lab & Blood	16.0%
Imaging	14.9%
Non-Invasive Procedures	10.0%
Routine Procedures	4.5%
Medication Dispensing	0.0%
Other	12.1%

Source: Tufts CSDD, 2025

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Reasons for Conducting Non-Core Procedures

Reason	Phase II	Phase III	Oncology	Non-Oncology
Safety	19.7%	21.4%	10.9%	23.5%
Future Use	23.7%	18.8%	23.4%	19.8%
Exploratory	21.9%	15.9%	43.1%	11.3%
Quality of Life/Symptom Evaluation/PRO	5.3%	13.3%	2.9%	12.5%
Efficacy	5.7%	10.8%	10.2%	8.7%
Market Differentiation	9.6%	5.8%	2.9%	8.3%
Support Reimbursement	4.8%	5.1%	1.5%	5.9%
Regulatory Request	0.4%	3.1%	1.5%	2.4%
PK/PD	2.2%	1.2%	1.5%	1.6%
Screening	0.9%	0.0%	0.0%	0.4%
Other	5.7%	4.6%	2.2%	5.7%

Note: *Yellow highlights the highest reason for conducting non-core procedures in each trial type*

Source: Tufts CSDD, 2025

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Data Included in the Clinical Study Report

Endpoint Classification	Main Body		Appendix			Total
	Discussed	Referenced	Discussed	Referenced	Included but not Discussed or Referenced	
Core	58.9%	16.7%	2.3%	12.8%	1.2%	92%
Standard/Required	45.0%	14.8%	0.8%	11.7%	4.7%	77%
Non-Core	46.5%	15.3%	1.5%	8.0%	2.9%	74%

Top Reasons Non-Core Procedure Data was Not Included (*percent reported*):

- Exploratory (28%)
- Future Use (27.7%)
- Safety (13.8%)

Source: Tufts CSDD, 2025

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Contribution of Non-Core Procedures to Participant and Site Burden

	Phase II	Phase III
PARTICIPANT BURDEN		
Non-Core Procedures	19.8%	16.7%
SITE BURDEN		
Non-Core Procedures	18.1%	16.6%

Smith et al. Enhancing the measure of participation burden in protocol design to incorporate logistics, lifestyle and demographic characteristics. TIRS. 2021; 55(6): 1239-1249

Florez et al. Quantifying site burden to optimize protocol performance. TIRS. 2024; 58(2): 347-356

Source: Tufts CSDD, 2025

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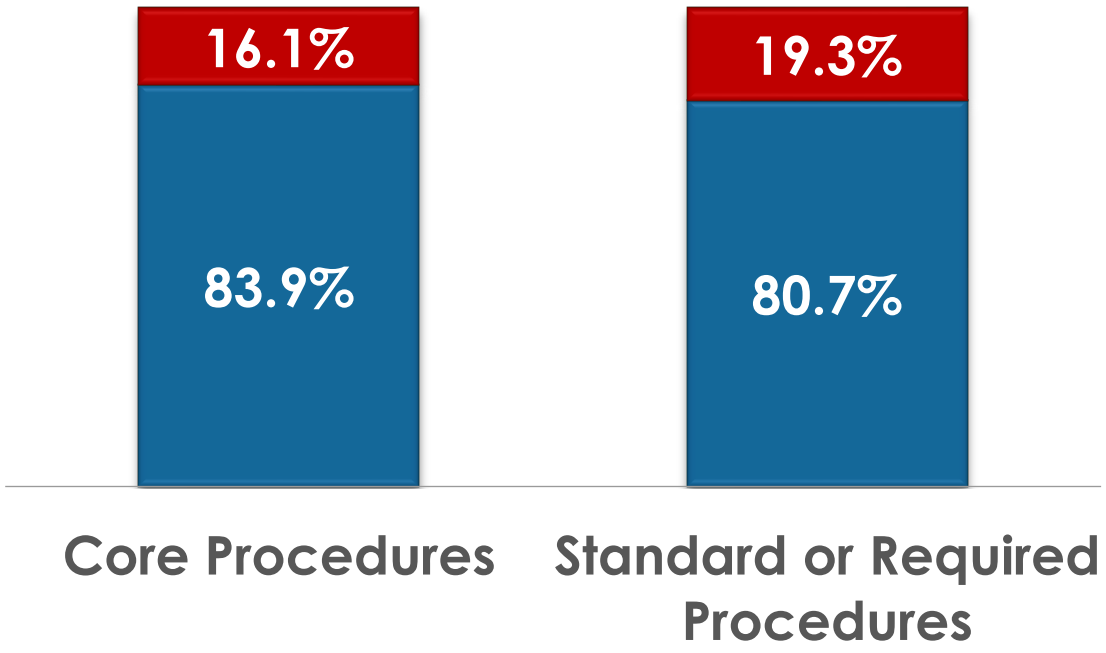
Introducing a New Measure: 'Non-Essential Procedures'

Non-Essential Procedures

Procedures determined by the clinical team or protocol authors as being conducted more times than necessary to demonstrate a clinical outcome, fulfill a regulatory requirement or support standard/routine procedures

Mean percent of datapoints collected per participant by Endpoint Category



Source: Tufts CSDD, 2025

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Contribution of Datapoints from Non-Core and Non-Essential Procedures

(Phase II/III Clinical Trials)	Datapoints per Participant from Non-Core Procedures	Datapoints per Participant from Non-Essential Core, Standard/Required Procedures	Total
Questionnaires	37.1%	18.3%	55.4%
Patient Diaries	37.5%	3.5%	41.0%
Invasive Procedures	25.9%	7.1%	33.0%
Lab & Blood	16.0%	13.4%	29.4%
Imaging	14.9%	6.1%	21.0%
Non-Invasive Procedures	10.0%	17.1%	27.1%
Routine Procedures	4.5%	11.9%	16.4%
Medication Dispensing	0.0%	3.1%	3.1%
Other	12.1%	1.9%	14.0%

Source: Tufts CSDD, 2025

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Contribution of Non-Core and Non-Essential Core, Standard or Required Procedures to Participant and Site Burden

	Phase II	Phase III
PARTICIPANT BURDEN		
Non-Core Procedures	19.8%	16.7%
Non-Essential Core, Standard or Required Procedures	5.9%	12.7%
TOTAL	25.7%	29.4%
SITE BURDEN		
Non-Core Procedures	18.1%	16.6%
Non-Essential Core, Standard or Required Procedures	7.0%	12.9%
TOTAL	25.1%	29.5%

Source: Tufts CSDD, 2025

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Summary Key Takeaways from this Study

- More than **one-third** of all data collected comes from **non-core and non-essential procedures**
- Non-core and non-essential procedures contribute to **25-30% of total participant and site burden**

  There may be other benefits so some non-essential procedures, for example, making sure patients are heard through site questionnaires.
- The majority (74%) of non-core data – much of it **exploratory and/or intended for future use** – appears in the Clinical Study Report
- Study results provide additional empirical evidence and insights encouraging **protocol design discussion and a shift in mindset** towards more intentional and **fit-for-purpose** data collection strategies
- These study results inform the development of **tools and frameworks** to support optimizing data collection

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Optimizing Data Collection: Proposed Solutions

Current Data

TransCelerate – Tufts CSDD Publication

Results provide empirical evidence and insights encouraging protocol design discussion and a shift in mindset towards more intentional and fit-for-purpose data collection strategies

View our preprint here!

Proposed Solutions

Planning Frameworks

Help sponsors strategically think through what to prioritize when optimizing data collection

Collection Assessment Tools

Increases visibility proactively on the impacts of procedure choices and frequency.

Desired Impact

To **reduce unnecessary burden** on patients, sites, regulators, and other stakeholder by helping sponsors **critically assess what data are collected and why**, while balancing scientific, operational, and regulatory demands.

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