

Building Standardized Evidence for eSource-Enabled Clinical Trials: Multi-Site Validation of a Clinical Research Coordinator Satisfaction Methodology

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Standardized measurement across five oncology centers found that clinical research coordinators rated eSource-enabled workflows positively (Overall Mean Satisfaction 5.79 of 7), with reduced manual entry and electronic data transfer earning strong marks, while perceived reduction in sponsor and monitor queries lagged as the one domain below threshold.

Abstract

BACKGROUND. Electronic health record-to-electronic data capture (EHR-to-EDC), commonly referred to as eSource, has emerged as a transformative approach for reducing manual data transcription, improving data quality, and decreasing operational burden in clinical trials. While numerous implementation studies have demonstrated promising operational benefits, broader adoption has been constrained by the lack of standardized methodologies capable of generating reproducible and comparable evidence across sponsors, investigational sites, and technology platforms. To address this gap, the European Institute for Innovation through Health Data (i~HD) eSource Scale-Up Task Force developed a harmonized key performance indicator (KPI) framework together with standardized methodologies for measuring implementation outcomes. This study presents the first multi-site validation of the Task Force's standardized clinical research coordinator (CRC) Satisfaction methodology.

METHODS. This observational, multi-center study applied the standardized CRC Satisfaction methodology across five leading academic oncology research centers in North America and Europe. A total of 28 anonymous

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CRC survey responses were collected during a four-month observation period from 5 April to 5 August 2025. The methodology, developed collaboratively by research hospitals, sponsors, and technology providers within the i~HD eSource Scale-Up Task Force, employs a standardized 7-point Likert survey evaluating system usability, workflow efficiency, confidence in electronic data transfer, perceived reduction in site burden, and overall job satisfaction. Results were aggregated and analyzed using predefined scoring criteria to enable consistent comparison across institutions.

RESULTS. Overall CRC satisfaction exceeded the predefined performance threshold, with an Overall Mean Satisfaction Score of 5.79 and a Positive Response Rate of 84%. Eight of nine survey domains exceeded the predefined positive implementation threshold (≥5), and all five participating research centers achieved overall mean satisfaction scores above the benchmark. Respondents reported positive experiences with workflow efficiency, electronic data transfer, and reduced manual data entry. The standardized methodology was successfully applied across diverse institutional settings, demonstrating its ability to generate reproducible and comparable implementation evidence.

CONCLUSIONS. This study represents the first multi-site validation of a standardized methodology for measuring CRC experience in eSource-enabled clinical trials. Beyond demonstrating positive implementation outcomes, it establishes the first building block of an evidence infrastructure capable of generating standardized, reproducible, and comparable evidence across eSource implementations. Such an evidence infrastructure can support benchmarking, organizational learning, regulatory dialogue, and the evidence-based adoption of eSource-enabled clinical research.

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"Interoperability enables implementation; standardized evidence enables adoption."

1. Introduction

1.1 FROM IMPLEMENTATION TO EVIDENCE

Clinical research is undergoing rapid digital transformation. Increasing protocol complexity, expanding data volumes, and growing regulatory expectations have accelerated the adoption of digital technologies designed to improve trial efficiency and data quality.[1,2] Among these, electronic health record-to-electronic data capture (EHR-to-EDC), commonly referred to as eSource, has emerged as one of the most promising approaches for integrating routine healthcare data directly into clinical research workflows.[3]

Early implementations have demonstrated the potential to reduce manual transcription, improve data quality, decrease source data verification effort, and reduce the operational burden placed on clinical research coordinators (CRCs).[4] Previous studies, including work conducted at Memorial Sloan Kettering Cancer Center, have shown that manual transcription remains one of the most resource-intensive activities at investigational sites and that EHR-to-EDC integration offers substantial opportunities to improve efficiency while maintaining regulatory compliance.

TABLE 1. Standardized CRC Satisfaction Instrument used in eSource-enabled clinical trials

No.	Survey Item (7-point Likert scale: 1 = Strongly Disagree to 7 = Strongly Agree)	Construct Measured
1	The eSource data transfer workflow was easy to learn.	Learnability
2	It is easy to transfer data to the EDC using the eSource system. Measured	Ease of Use
3	The eSource system correctly retrieves patient data.	Confidence and Trust
4	I know which clinical data can be transferred electronically.	System Awareness
5	I have received fewer sponsor/site monitor queries since using the eSource system.	Data Quality
6	Transferring data electronically is less time-consuming than manual entry.	Perceived Time Savings
7	Transferring data electronically is more efficient than manual data entry.	Perceived Efficiency
8	I prefer electronic transfer over manual data entry.	Preference / Adoption
9	My overall job satisfaction has increased since using the eSource system.	Job Satisfaction

Two additional open-ended questions capture qualitative feedback on implementation challenges and suggestions for improvement.

These studies have established the technical feasibility and operational promise of eSource.[5] Despite these advances, an important challenge remains. Most published evidence describing eSource implementations consists of individual case studies, pilot projects, or vendor-specific evaluations. Although valuable, these studies often use different methodologies, different outcome measures, and different definitions of success, making comparisons across sponsors, hospitals, and technology platforms difficult. Therefore, the evidence supporting eSource adoption remains fragmented and difficult to aggregate.

The challenge facing the field is therefore no longer simply how to implement eSource, but how to generate standardized evidence that implementation has been successful. Such standardized evidence enables meaningful benchmarking across organizations, supports identification of implementation improvement opportunities, and contributes to the accumulation of reproducible evidence for large-scale adoption.

1.2 The need for standardized evidence

The widespread adoption of any healthcare innovation depends on more than technological capability. Sustainable implementation requires trusted evidence demonstrating value across different organizations, healthcare systems, and implementation environments.

This principle is particularly relevant for eSource-enabled clinical trials. While interoperability standards such as HL7® FHIR®[6,7] enable standardized exchange of clinical information, no comparable framework has existed for generating standardized evidence regarding implementation outcomes. Without harmonized methodologies, each implementation remains an isolated success story rather than contributing to a cumulative, reproducible body of implementation evidence.8

Recognizing this challenge, the European Institute for Innovation through Health Data (i~HD) established the *eSource Scale-Up Task Force in 2024*.[3] Bringing together pharmaceutical sponsors, academic research hospitals, technology providers, and interoperability experts, the Task Force was created to accelerate evidence-based adoption of eSource through neutral, consensus-driven methodologies rather than technology-specific recommendations.

The Task Force has progressively developed the scientific and methodological foundations required for large-scale implementation, including Early Adopters' Minimum Criteria for Success, a standardized key performance indicator (KPI) framework, and the eSource Playbook describing implementation principles across the clinical trial lifecycle. Together, these deliverables established what should be implemented and what should be measured.[9,10]

The next challenge was to determine how implementation outcomes should be measured in a standardized manner.

1.3 From KPIs to standardized evidence generation

Building upon the standardized KPI framework, the Task Force subsequently developed harmonized methodologies for measuring individual implementation outcomes across sponsors, investigational sites, and technology providers.[9]

Among these, CRC Satisfaction and Perceived Site Burden were identified as one of the most important early indicators of successful implementation. CRCs occupy a central role within clinical trial operations, and their experience reflects not only system usability but also workflow integration, operational efficiency, trust in automated data transfer, and the long-term sustainability of eSource implementation.

To enable meaningful comparison across studies and organizations, the Task Force developed a standardized CRC Satisfaction methodology based on predefined survey constructs, harmonized scoring principles, and common reporting standards.[11] The methodology was designed to be

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TABLE 2. Standardized Scoring and Interpretation Framework for the CRC Instrument.

Metric	Definition	Purpose	Construct Measured
1. Overall Mean Satisfaction Score	Mean score across all 9 closed-ended survey items (7-point Likert scale: 1 = Strongly Disagree to 7 = Strongly Agree).	Primary measure of overall CRC satisfaction with eSource-enabled workflows.	Learnability
2. Positive Response Rate (Satisfaction Score)	Percentage of all responses scoring 5-7 on the 7-point Likert scale.	Standardized measure of positive CRC experience enabling comparison across studies, sites, and institutions.	Ease of Use
3. Individual Item Mean	Mean score for each of the 9 survey items.	Identifies strengths and opportunities for improvement within specific implementation domains.	Confidence and Trust
4. Response Distribution	Frequency (%) of responses for each Likert category (1-7) for each item and overall.	Evaluates response variability and detects potential ceiling or floor effects.	System Awareness
5. Qualitative Responses	Thematic analysis of responses to the 2 open-ended survey questions.	Provides contextual understanding of quantitative findings and identifies implementation themes.	Data Quality

Two additional open-ended questions capture qualitative feedback on implementation challenges and suggestions for improvement.

Overall Mean Satisfaction Score	Interpretation
6.0 – 7.0	Excellent implementation experience
5.0 – 5.9	Good implementation experience
4.0 – 4.9	Moderate implementation experience<
< 4.0	Opportunity for implementation improvement

Key Points

- Higher scores indicate better CRC experience and lower perceived site burden.
- A target Overall Mean Satisfaction Score of ≥ 5.0 reflects a good implementation experience.
- Interpretation thresholds were established through expert consensus within the i~HD eSource Scale-Up Task Force during development of the standardized methodology.

Interpretation thresholds are intended to support consistent evaluation and benchmarking across studies and institutions. They may be refined as additional evidence becomes available.

technology-independent and applicable across diverse implementation environments, thereby enabling reproducible evidence generation and future benchmarking. Rather than evaluating a specific technology platform, the methodology provides a common framework for measuring implementation outcomes using standardized metrics.

1.4 Study objective

The future success of eSource will depend not only on interoperability and automation, but also on the ability to generate standardized, reproducible evidence across implementations.

The objective of this study is to present the first multi-site validation of the standardized CRC Satisfaction methodology developed by the i~HD eSource Scale-Up Task Force. Using 28 anonymous CRC survey responses collected across five leading academic oncology research centers, the study evaluates whether standardized implementation outcomes can be measured consistently across independent institutions and establishes the first building block of an evidence infrastructure for eSource-enabled clinical trials.

2. Methods

2.1 STUDY DESIGN

This study used an observational, multi-center design to evaluate the applicability and reproducibility of the standardized CRC Satisfaction methodology developed by the i~HD eSource Scale-Up Task Force.

The study represents the first multi-site application and validation of the methodology across multiple academic research institutions and oncology clinical trials. Importantly, the objective was not to evaluate the performance of a specific eSource technology platform, but to determine whether a

TABLE 3. Study population and participating research centers

Research Center	CRC Survey Responses (n)
Memorial Sloan Kettering Cancer Center (MSKCC)	14
UT MD Anderson Cancer Center	4
City of Hope Comprehensive Cancer Center (COH)	3
Mayo Clinic Comprehensive Cancer Center (MCCCC)	5
University College London Hospitals (UCLH)	2
Total	**28**

CRC, Clinical Research Coordinator; n, number of anonymous survey responses.

standardized methodology could generate comparable implementation evidence across independent organizations.

2.2 Development of the standardized methodology

The CRC Satisfaction methodology was developed within the i~HD eSource Scale-Up Task Force as part of a broader initiative to establish standardized methodologies for evaluating implementation outcomes in eSource-enabled clinical trials. The methodology builds upon the Task Force's previously published KPI framework, which identified CRC Satisfaction and Perceived Reduced Site Burden as one of the priority indicators for evaluating successful eSource implementation.

Development of the methodology followed an iterative multi-stakeholder consensus process coordinated by the i~HD eSource Scale-Up Task Force. The methodology was developed by the same core group of nine founding organizations that had previously established the Task Force's standardized KPI framework and contributed to the development of the eSource Playbook. This core group comprised five pharmaceutical sponsors (AstraZeneca, Johnson & Johnson, Sanofi, Regeneron, and Lilly) and four leading academic oncology research centers (Memorial Sloan Kettering Cancer Center, University Hospital of Cambridge, University Hospital of Essen, and Mayo Clinic Comprehensive Cancer Center), working in collaboration with i~HD and technology providers.

Draft survey constructs, implementation domains, scoring principles, interpretation thresholds, and reporting recommendations were reviewed during structured Task Force meetings and refined through successive iterations until consensus was achieved. Throughout the development process, emphasis was placed on ensuring that the methodology reflected practical implementation experience while remaining technology-independent, scientifically robust, and broadly applicable across diverse implementation environments.

The methodology defines standardized survey constructs, response scales, scoring principles, interpretation thresholds, and reporting recommendations to ensure comparability across studies and institutions.

2.3 Participating research centers

The evaluation was conducted across five leading academic oncology research centers in North America and Europe. Participating institutions were:

- Memorial Sloan Kettering Cancer Center (MSK)
- Mayo Clinic Comprehensive Cancer Center (MCCCC)
- UT MD Anderson Cancer Center
- City of Hope Comprehensive Cancer Center
- University College London Hospitals NHS Foundation Trust (UCLH)

These institutions represent early adopters of eSource technologies and participate in the i~HD eSource Scale-Up Task Force reference groups.

2.4 Implementation environment

Participating studies implemented EHR-to-EDC integration using Archer™ (IgniteData), a commercially available EHR-to-EDC platform that enables standards-based transfer of structured clinical data from EHRs to EDC systems.[4] Archer served as the common implementation environment across participating studies, providing a consistent operational setting for application of the standardized CRC Satisfaction methodology.

The evaluated eSource-enabled workflows supported routine data transfers during scheduled patient visits throughout active study conduct, depending on the protocol-specific visit schedule of each participating trial. Importantly, the objective of this study was not to evaluate the Archer platform itself, but to evaluate the applicability and reproducibility of a standardized methodology for measuring implementation outcomes in eSource-enabled clinical trials. The methodology has been created to be technology-independent and applicable across different EHR-to-EDC implementation platforms.

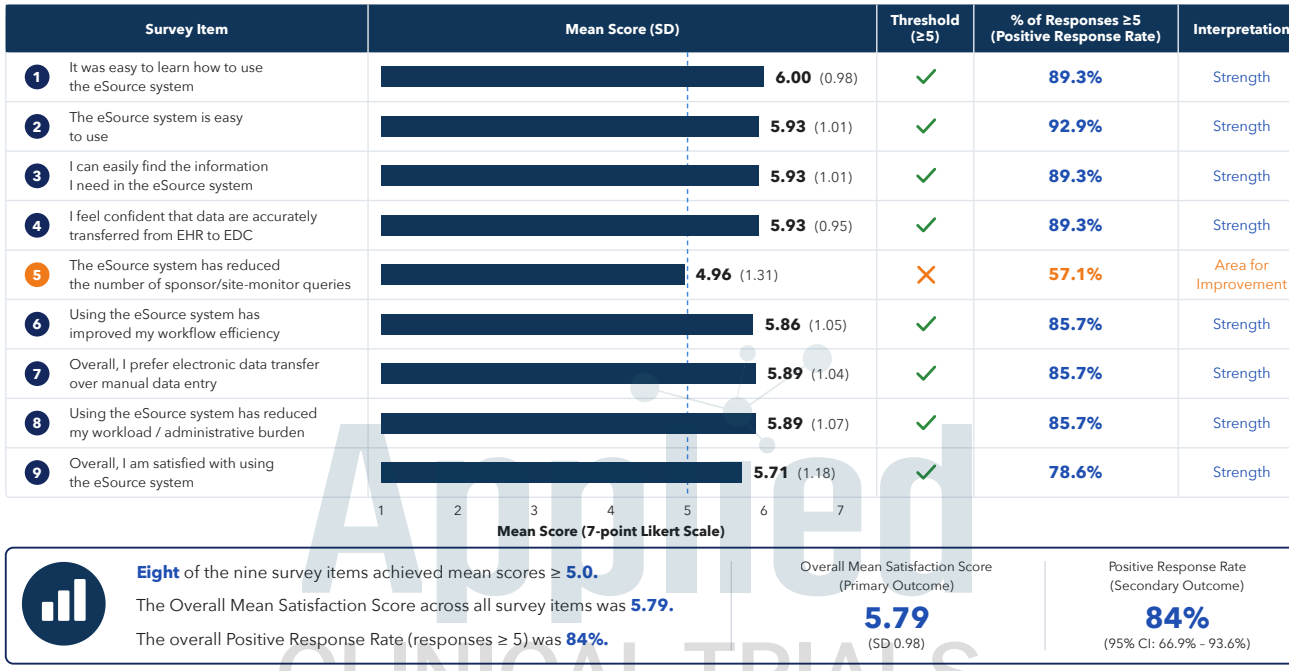
2.5 CRC Satisfaction Survey

The standardized CRC Satisfaction Instrument[11] represents the first standardized methodology developed by the i~HD eSource Scale-Up Task Force for evaluating end-user experience and perceived site burden in eSource-enabled clinical trials. Developed using the methodology described in Section 2.2, the instrument provides a technology-independent and reproducible approach for measuring implementation

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FIGURE 1. Standardized measurement of CRC Experience across five oncology research centers

Responses are based on the standardized 9-item CRC Satisfaction Instrument (7-point Likert scale; N = 28 survey responses)



CRC, Clinical Research Coordinator; EHR, electronic health record; EDC, electronic data capture; SD, standard deviation.
Positive Response Rate defined as the percentage of responses scoring 5-7 on the 7-point Likert scale.

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outcomes across different EHR-to-EDC implementation platforms and clinical research environments.

The instrument consists of nine standardized closed-ended survey items and two open-ended questions, addressing five key implementation domains: system usability, workflow efficiency, confidence in electronic data transfer, perceived reduction in site burden, and overall job satisfaction. The two open-ended questions invited respondents to describe (1) the principal benefits they experienced when using eSource-enabled workflows and (2) recommendations for future improvements. The standardized survey items and their corresponding implementation constructs are presented in Table 1.

All closed-ended items were evaluated using a 7-point Likert scale, ranging from 1 (Strongly Disagree) to 7 (Strongly Agree). The open-ended responses were collected to provide qualitative insights into implementation experiences, perceived benefits, challenges, and recommendations for future improvements.

The instrument was intentionally designed to be technology-independent, allowing its application across different EHR-to-EDC implementation platforms and clinical research environments. Standardization of the survey instrument provides the foundation for reproducible measurement and future benchmarking of implementation outcomes across studies, institutions, and technology providers.

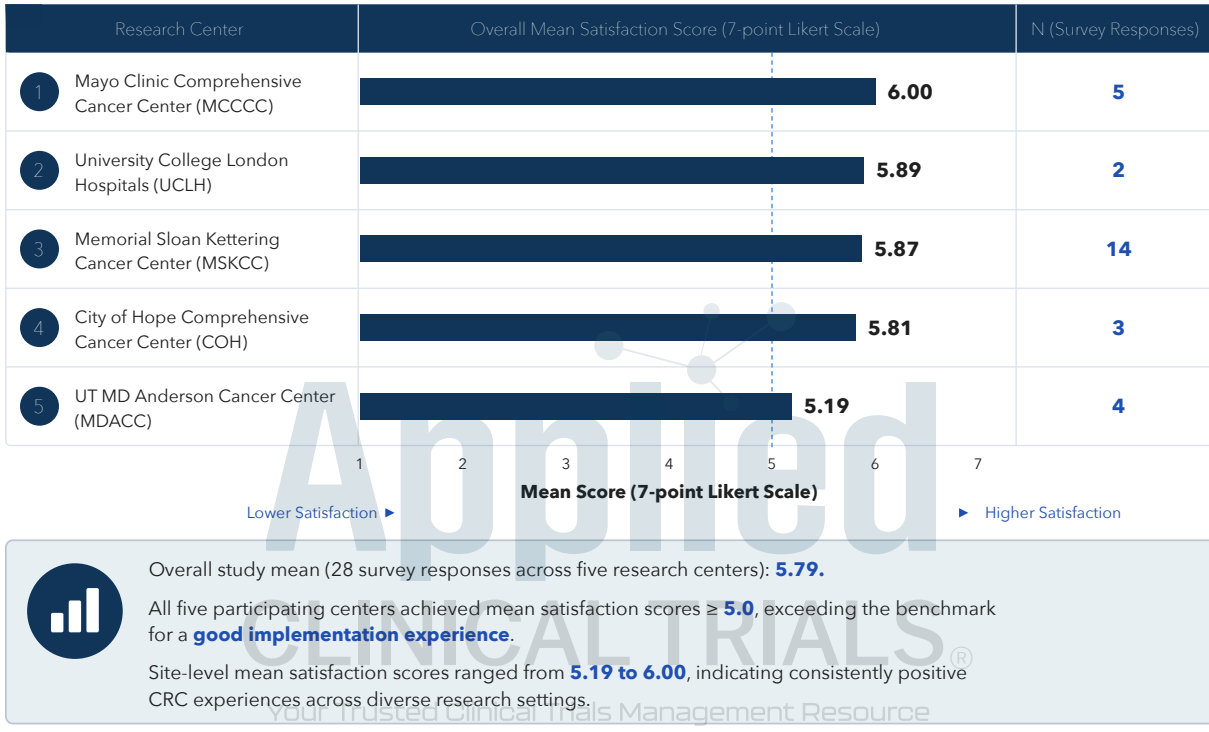
Eligible respondents were CRCs with hands-on experience using eSource-enabled workflows for a minimum of three weeks. Survey administration followed the standardized methodology developed by the Task Force to ensure consistency across participating institutions.

2.6 Data collection and analysis

Data collection was conducted prospectively during a predefined four-month observation period from 5 April to 5 August 2025. To minimize selection bias, each participating research center identified eligible oncology clinical trials with active eSource-enabled workflows and scheduled patient visits occurring within this observation period. CRCs involved in these eligible studies were invited to complete the standardized CRC Satisfaction survey following a minimum of three weeks of hands-on experience using eSource-enabled workflows. Eligible studies were identified prospectively according to the predefined observation period and the availability of active eSource-enabled workflows, rather than

FIGURE 3. Reproducibility of the Standardized CRC Satisfaction Methodology across five academic research centers (N=28).

Overall mean CRC satisfaction scores calculated using standardized 9-item CRC Satisfaction Instrument (7-point Likert scale). The dashed line indicates the pre-defined positive implementation threshold (Score greater than/equal to 5).



Overall study mean (28 survey responses across five research centers): **5.79.**

All five participating centers achieved mean satisfaction scores ≥ **5.0**, exceeding the benchmark for a **good implementation experience**.

Site-level mean satisfaction scores ranged from **5.19 to 6.00**, indicating consistently positive CRC experiences across diverse research settings.

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Note: Distribution of survey responses: MSKCC 14; MCCCC 5; MDACC 4; COH 3; UCLH 2.

CRC, Clinical Research Coordinator; EHR, electronic health record; EDC, electronic data capture.

based on implementation performance or survey outcomes. Survey responses were collected anonymously; consequently, individual responses could not be linked to specific CRC identities or uniquely attributed to individual clinical trials.

Results were therefore analyzed at the survey-response and institutional levels. To ensure reproducible and comparable evaluation across studies and institutions, the i~HD eSource Scale-Up Task Force developed a standardized scoring and interpretation framework for the CRC Satisfaction Instrument. The framework defines common outcome measures, scoring principles, interpretation criteria, and reporting recommendations, enabling consistent assessment of implementation outcomes across different eSource-enabled clinical trial environments.

The standardized framework[11] comprises one primary outcome measure and four complementary secondary outcome measures (Table 2). Together, these provide a balanced assessment of overall user experience, implementation performance, and contextual factors influencing successful adoption.

The primary outcome measure was the Overall Mean Satisfaction Score, calculated as the mean response across all closed-ended survey items using the standardized seven-point Likert scale. The secondary outcome measures included the Positive Response Rate (Satisfaction Score), defined as the proportion of responses scoring [5-7] on the seven-point Likert scale; Individual Item Mean Scores, enabling evaluation of specific implementation domains; Response Distribution, describing variability across response categories; and Qualitative Responses, derived from thematic analysis of the open-ended survey questions.

As summarized in Table 2, standardized interpretation criteria were established through expert consensus within the i~HD eSource Scale-Up Task Force during development of the methodology. These criteria provide a common framework for interpreting survey results and support benchmarking across studies, institutions, and future eSource implementations.

TABLE 4. Representative themes from open-ended CRC responses.

Overall mean CRC satisfaction scores calculated using standardized 9-item CRC Satisfaction Instrument (7-point Likert scale). The dashed line indicates the pre-defined positive implementation threshold (Score greater than/equal to 5).

Theme	Illustrative CRC Comments (summarized)
Workflow Efficiency and Time Savings	• Respondents consistently described reduced manual transcription, more streamlined workflows, and increased time available for higher-value research activities. • Several noted that eSource enabled them to spend less time on routine data entry and more time supporting patients and study conduct. • Perceived time savings depended on the proportion and type of study data available for electronic transfer; studies with more transferable data points provided greater efficiency benefits, while those with fewer transferable items provided more limited time savings.
Preference for Electronic Data Transfer	• Many CRCs expressed a clear preference for electronic transfer compared with manual transcription, describing the process as easier, faster, and something they would prefer to continue using in future studies.
Confidence in Transferred Data	• Respondents frequently reported greater confidence in the transferred clinical data, highlighting improved consistency and fewer transcription-related errors compared with manual entry.
Reduced Administrative Burden	• Several comments emphasized reductions in duplicative documentation, repetitive work, and administrative effort. • This contributed to a more efficient integration between routine clinical care and research documentation.
Suggestions for Further Improvement	• Suggestions focused on expanding the range of automatically transferred data elements, improving workflow transparency and user notifications, and continuing user training. • Respondents highlighted these areas as important to support broader adoption and consistent implementation across studies.

Note: 24 of 28 respondents (86%) provided at least one comment to the primary open-ended question regarding challenges and difficulties. 20 of 28 respondents (71%) provided comments to the secondary open-ended question regarding additional feedback, and 22 of 28 respondents (79%) answered both open-ended questions.

Abbreviations: CRC, Clinical Research Coordinator; EHR, Electronic Health Record; EDC, Electronic Data Capture.

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2.7 Role of the i~HD eSource Scale-Up Task Force

The standardized methodology evaluated in this study was developed through the governance structure of the i~HD eSource Scale-Up Task Force.

The Task Force brings together pharmaceutical sponsors, academic research hospitals, technology providers, and interoperability experts to develop neutral, consensus-based methodologies that support evidence-based scale-up of eSource-enabled clinical trials. Within this governance model, technology providers contribute implementation experience and technical expertise alongside sponsors and research sites, while standardized methodologies are developed through multi-stakeholder consensus and are intended to remain independent of any individual technology platform.

3. Results

3.1 STUDY POPULATION

A total of 28 anonymous CRC Satisfaction survey responses were collected across five academic oncology research centers in North America and Europe. Because survey responses were collected anonymously, individual responses could not be linked to specific CRC identities or uniquely attributed to individual clinical trials. Results are therefore reported at the survey-response and institutional levels.

The responses were distributed across the participating institutions as follows: Memorial Sloan Kettering Cancer Center (MSK), 14 responses; Mayo Clinic Comprehensive Cancer Center, 5 responses; UT MD Anderson Cancer Center, 4 responses; City of Hope Comprehensive Cancer Center, 3 responses; and University College London Hospitals NHS Foundation Trust (UCLH), 2 responses (Table 3).

The survey responses reflected an experienced user population. Nineteen of the 28 responses (68%) were from CRCs reporting more than two years of clinical research experience. Twenty-five respondents (89%) reported having performed more than five electronic data transfers using the eSource platform, including 11 (39%) who reported more than 50 transfers. This level of prior exposure indicates that the survey responses predominantly reflected sustained practical experience with eSource-enabled workflows rather than initial impressions from novice users.

3.2 Standardized measurement of CRC experience

Across the 28 survey responses, the standardized CRC Satisfaction methodology demonstrated consistently positive implementation outcomes.

The Overall Mean Satisfaction Score was 5.79, exceeding the predefined benchmark of ≥5 for a good implementation experience. The Positive Response Rate was 84%, indicating that most responses across the standardized survey items were rated Slightly Agree, Agree, or Strongly Agree.

Eight of the nine standardized survey items achieved mean scores above the predefined threshold of ≥5. The highest mean score was observed for ease of learning (6.00), with similarly high ratings for ease of electronic data transfer (5.93), correct retrieval of patient data (5.93), and understanding which laboratory and vital-sign data were transferable (5.93). CRCs also reported positive experiences regarding workflow efficiency (5.89), preference for electronic rather than manual data transfer (5.89), reduced time spent on manual data entry (5.86), and overall job satisfaction (5.71).

Perceived reduction in sponsor/site-monitor queries was the only item marginally below the predefined threshold (mean 4.96; SD 1.31). The comparatively higher variability and a Positive Response Rate of 57.1% indicate heterogeneous experiences across respondents, suggesting that query reduction may depend on implementation- and study-specific factors beyond electronic data transfer alone.

Overall, the findings indicate that the standardized methodology captured strongly positive CRC experiences across most implementation domains while also identifying an outcome—query reduction, for which respondent experiences were more variable. The results are summarized in Figure 1.

3.3 Cross-site reproducibility

One of the principal objectives of this study was to evaluate whether the standardized CRC Satisfaction methodology could be applied consistently across independent research organizations. Despite differences in organizational structure, clinical workflows, implementation maturity, and study portfolios, the standardized methodology generated interpretable site-level results across the five participating oncology research centers. As illustrated in Figure 2, all five participating institutions achieved Overall Mean Satisfaction Scores above the predefined benchmark for a good implementation experience (≥5), with site-level mean scores ranging from 5.19 to 6.00.

The highest Overall Mean Satisfaction Score was observed at Mayo Clinic Comprehensive Cancer Center (6.00), followed by UCLH (5.89), MSKCC (5.87), City of Hope (5.81), and UT MD Anderson Cancer Center (5.19). While all centers exceeded the predefined benchmark, the observed variation demonstrates that the standardized methodology can capture differences in implementation experience using a common measurement and interpretation framework.

These findings support the consistent application of the standardized methodology across diverse organizational settings and its potential to generate comparable implementation evidence for future benchmarking and multi-site evidence generation.

3.4 Qualitative findings

Thematic analysis of the open-ended survey responses identified several recurring implementation themes. The most frequently reported benefits included:

- Reduced manual transcription
- Improved workflow efficiency
- Increased confidence in electronic data transfer
- Preference for electronic rather than manual data entry
- Reduced administrative burden

Respondents also identified opportunities for continued improvement, including broader availability of electronically transferable data, increased automation of clinical workflows, enhanced user feedback during data transfer, and additional end-user training.

The qualitative responses also provided important context for the quantitative findings on reduced time spent on manual data entry. Respondents indicated that perceived time savings depended partly on the proportion and type of study data available for electronic transfer. Studies or workflows involving relatively few transferable data points were perceived to provide more limited time savings, whereas more data-intensive workflows were expected to offer greater efficiency benefits. These observations suggest that the operational benefits of eSource may increase as the scope of electronically transferable data expands. Representative qualitative responses are summarized in Table 4.

3.5 Validation of the standardized methodology

Application of the standardized CRC Satisfaction Instrument across 28 anonymous survey responses collected at five independent academic research centers demonstrated that the methodology could generate standardized and comparable implementation evidence across diverse organizational settings.

Specifically, the standardized methodology successfully:

- Generated consistent implementation outcome measures using predefined measurement and scoring principles;
- Produced comparable evidence across multiple research institutions;
- Identified implementation strengths and opportunities for improvement;

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- Supported standardized benchmarking across sites; and
- Demonstrated the feasibility of harmonized evidence generation using common measurement principles.

Collectively, these findings represent the first multi-site validation of the standardized CRC Satisfaction methodology developed by the i~HD eSource Scale-Up Task Force and establish the first building block of an evidence infrastructure for eSource-enabled clinical trials.

4. Discussion

4.1 PRINCIPAL FINDINGS

This study represents the first multi-site validation of a standardized methodology for measuring CRC experience in eSource-enabled clinical trials. Application of a common measurement instrument and standardized scoring framework across 28 anonymous survey responses collected at five leading academic research centers demonstrated that implementation outcomes can be measured consistently across independent organizations.

The findings extend beyond demonstrating positive user experience. They show that standardized implementation outcomes can be generated consistently using common measurement principles, thereby enabling meaningful comparison and benchmarking across institutions. This represents an important methodological advance for evaluating eSource implementations and provides a foundation for future evidence generation.

4.2 Comparison with previous eSource literature

Published evidence describing eSource implementations has largely focused on technical feasibility, workflow optimization, and operational benefits within individual institutions or implementation programs. Earlier studies, including our previous work at Memorial Sloan Kettering Cancer Center and the subsequent multi-center evaluation across five international oncology research centers, demonstrated that EHR-to-EDC integration can reduce manual transcription, improve workflow efficiency, and decrease CRC burden.[4,5]

However, differences in study design, outcome measures, and reporting methodologies have limited the ability to compare findings across organizations or aggregate evidence across implementations. The present study extends previous work by applying a standardized measurement instrument and scoring framework across multiple independent oncology centers. Rather than evaluating a single implementation, it demonstrates that implementation outcomes can be measured consistently using common scientific principles, thereby supporting standardized and comparable evidence generation across diverse research environments.

4.3 Implications for standardized evidence generation

One of the principal challenges facing large-scale adoption of eSource is the absence of standardized methodologies for evaluating implementation success. While interoperability standards enable the technical exchange of clinical data, they do not by themselves provide evidence that implementations achieve consistent operational benefits across organizations.

The standardized CRC Satisfaction Instrument addresses one component of this challenge by providing a common methodology for measuring end-user experience and perceived site burden. Application of a common measurement framework allows implementation outcomes to be compared across studies, institutions, and implementation environments, supporting standardized evidence generation and future benchmarking.[11,12]

Importantly, application of the standardized methodology produced interpretable site-level results across all five participating research centers. Overall Mean Satisfaction Scores ranged from 5.19 to 6.00, with all five centers exceeding the predefined benchmark for a good implementation experience (≥5). While the results were consistently positive, the observed variation across centers demonstrates that the methodology can quantify differences in implementation experience using a common measurement and interpretation framework.

The methodology also identified variation at the individual outcome level. Perceived reduction in sponsor/site-monitor queries was the only survey item marginally below the predefined threshold (mean 4.96; SD 1.31), with greater response variability than most other items. This illustrates the ability of the standardized instrument to identify specific implementation outcomes for which user experiences may be more heterogeneous, even when overall implementation experience is positive.

This capability is important for meaningful benchmarking and continuous quality improvement. As additional standardized methodologies are developed for the remaining priority KPIs within the i~HD eSource Scale-Up Task Force framework, comparable evidence can be generated across implementations, enabling organizations to measure progress consistently, identify best practices, and accumulate evidence at scale. Collectively, these methodologies will establish the foundations of an evidence infrastructure capable of supporting organizational learning, benchmarking, regulatory dialogue, and evidence-based adoption of eSource-enabled clinical trials.

4.4 Practical implications

For pharmaceutical sponsors, standardized implementation methodologies provide objective evidence supporting

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investment decisions and enable consistent evaluation across studies and research sites. For investigational sites, standardized benchmarking creates opportunities to monitor implementation maturity, identify areas for improvement, and share best practices across institutions.

For technology providers, common evaluation methodologies offer transparent and technology-independent frameworks for assessing implementation outcomes while encouraging continuous innovation and quality improvement.

Importantly, the methodology presented in this study was developed through the multi-stakeholder governance model of the i~HD eSource Scale-Up Task Force, involving pharmaceutical sponsors, academic research hospitals, technology providers, and interoperability experts. This collaborative approach was intended to ensure that standardized methodologies remain technology-independent while reflecting practical implementation experience across diverse stakeholder groups.

4.5 Study strengths and limitations

Several limitations should also be acknowledged. The study included a relatively modest number of survey responses and focused exclusively on oncology clinical trials conducted within a common implementation environment. Because survey responses were collected anonymously, individual responses could not be linked to unique CRC identities or attributed to individual clinical trials.

The analysis therefore reflects response-level and institutional-level experience rather than trial-level outcomes, and repeated participation by the same individual cannot be definitively excluded. In addition, site-level sample sizes were small and unequal, and comparisons between institutions should therefore be interpreted descriptively rather than inferentially.

Although the standardized methodology itself is technology-independent, further validation across additional therapeutic areas, healthcare systems, and EHR-to-EDC platforms will strengthen its generalizability. Larger validation studies may also investigate whether user satisfaction varies according to CRC experience, implementation maturity, or extent of hands-on use with eSource-enabled workflows. Such analyses could provide additional insights into factors influencing successful implementation and user adoption.

Future studies should also investigate how standardized implementation outcomes translate into broader value propositions for eSource adoption, including workflow efficiency, time savings, reduced administrative burden, improvements in data quality, resource utilization, and economic impact. Building on the KPI framework developed by the i~HD eSource Scale-Up Task Force,9 standardized methodologies are being progressively developed and validated for the remaining priority KPIs to support harmonized measurement of value across eSource-enabled clinical trials.

Collectively, these methodologies will establish a comprehensive evidence infrastructure capable of generating standardized, reproducible, and comparable evidence across the major dimensions of eSource implementation. Establishing these relationships will further strengthen the evidence base supporting large-scale implementation of eSource-enabled clinical trials.

5. Conclusions

This study represents the first multi-site validation of a standardized methodology for measuring CRC experience in eSource-enabled clinical trials. Application of a common survey instrument and standardized scoring framework across five leading academic oncology research centers demonstrated that implementation outcomes can be measured consistently across independent organizations using common measurement principles.

The methodology provides a template for validating additional standardized approaches for measuring KPIs within the i~HD eSource Scale-Up Task Force framework. Beyond validating a single implementation outcome, this study demonstrates how standardized methodologies can generate comparable implementation evidence across institutions and technology environments. The standardized CRC Satisfaction Instrument therefore represents the first validated building block of a broader evidence infrastructure for eSource-enabled clinical trials. Although validated in oncology research centers, the methodology was intentionally designed to measure generic implementation constructs and is expected to be applicable across a broad range of therapeutic areas and clinical research settings.

The findings also provide evidence that eSource-enabled workflows can improve workflow efficiency, reduce administrative burden, increase confidence in electronic data transfer, and achieve high levels of user acceptance among CRCs. As additional standardized methodologies are progressively developed and validated for the remaining priority KPIs within the i~HD eSource Scale-Up Task Force framework, future studies should investigate how implementation outcomes translate into broader value propositions, including workflow efficiency, time savings, data quality, resource utilization, and economic impact. Collectively, these methodologies can establish a comprehensive evidence infrastructure that supports benchmarking, organizational learning, and evidence-based scale-up of eSource-enabled clinical trials.

Interoperability enables implementation; standardized evidence enables adoption.

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