

Standardized Method for Measuring CRC Satisfaction in eSource-Enabled Trials

A deliverable from the i-HD eSource Scale Up Task Force
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Preface

In 2024, the European Institute for Innovation through Health Data (i~HD) launched the [eSource Scale Up Task Force](#), a milestone initiative aimed at transforming how clinical trial data is collected. This multidisciplinary group—bringing together industry leaders, healthcare professionals, and technology experts—was established to accelerate the global adoption of eSource technologies and drive more efficient, high-quality clinical trial execution.

This document is an extension of the i~HD deliverable, [Selected KPIs for eSource-Enabled Trials](#), which outlines key performance indicators to support the effective scale-up of eSource solutions. It provides a detailed methodology for KPI No. 5: “*User-Friendly CRC Experience & Perceived Reduced Site Burden*”, focusing on a standardized survey instrument designed specifically for Clinical Research Coordinators (CRCs) at investigational sites with hands-on experience using eSource systems.

The development of this methodology is the result of broad, cross-sector collaboration among leading institutions and companies, including Memorial Sloan Kettering Cancer Center, Cancer Research UK Cambridge Centre / Cambridge University Hospitals NHS Foundation Trust, University Hospital of Essen, AstraZeneca, Johnson & Johnson, Lilly, Regeneron, Sanofi, and i~HD. This diverse partnership ensures the framework is grounded in real-world implementation and applicable across varied clinical environments.

The objective is to establish this CRC survey as a standardized KPI for assessing CRC satisfaction with eSource systems—enabling consistent evaluation across trials, sites, sponsors, and vendors. Through broader application, the tool aims to build an evidence base that supports data-driven decision-making and continuous improvement in the deployment of eSource technologies.

1. Introduction

As clinical trials increasingly adopt eSource technology to streamline data collection from Electronic Health Records (EHR) to Electronic Data Capture (EDC) systems, understanding the experience of Clinical Research Coordinators (CRCs) has become essential. CRCs are key users of these systems, and their satisfaction reflects not only usability but also operational success.

This methodology is based on the KPI no 5 from the i-HD white paper on Selected eSource Key Performance Indicators (KPIs), which emphasizes the importance of a 'User-Friendly CRC Experience and Perceived Reduced Site Burden.' By integrating validated survey constructs from Memorial Sloan Kettering's eSource Electronic Data Transfer Feedback Survey and building on evaluations from the Applied Clinical Trials. July/August 2023 [eSource Interoperability Between EHR and EDC](#).

Standardizing how we measure CRC satisfaction is essential to enable consistent comparisons across trials, sites, sponsors, and vendors. Without a harmonized approach, insights cannot be easily shared, outcomes remain difficult to compare, and system improvements risk being misdirected. Annex 1 presents the recommended CRC satisfaction survey designed to support eSource-enabled trials, generate real-world evidence, and guide future scale-up.

2. Survey Design and Implementation

The proposed tool is a structured survey that captures both quantitative and qualitative feedback. It uses a 7-point Likert scale (1 = Strongly disagree, 7 = Strongly agree) for nine core items, and two open-ended questions to gather insight into challenges and suggestions for improvement. Questions evaluate usability, perceived efficiency, data quality, system trust, and job satisfaction. Eligible respondents are CRCs with hands-on experience using an eSource-enabled EDC system for at least three weeks. The survey should be administered post-implementation to capture the full user experience.

Component	Description
Respondent Group	CRCs with hands-on experience using the eSource system
Tool Format	Structured digital or paper survey
Response Scale	7-point Likert scale (1 = Strongly Disagree, 7 = Strongly Agree)
Timing	Post-pilot or after minimum 3 weeks of routine system use
Sample size	Typically, 2–3 Clinical Research Coordinators (CRCs) are assigned per study, with more involved in larger trials. For this survey, we recommend responses from at least two CRCs per study, ideally from all those assigned.

No	Survey Question	Measured Construct
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.	Ease of Use
3	The eSource software correctly retrieves patient data (e.g., labs & vital signs, name, DOB).	Confidence and Trust
4	I know which lab tests and/or vital signs are transferrable via the eSource system.	System Awareness
5	I have received fewer queries from the sponsor/site monitor since using the eSource system.	Data Quality
6	Transferring data through the eSource system is less time-consuming than manual entry.	Perceived Time Savings
7	Transferring data through the eSource system is more efficient than manual data entry.	Perceived Efficiency
8	I prefer transferring data electronically using the eSource system over manual entry.	Preference/Adoption
9	My overall job satisfaction has increased since using the eSource system.	Job Satisfaction
10	What challenges or difficulties have you experienced with transferring data electronically?	Improvement Areas
11.	Do you have any additional feedback to help us improve?	Open Feedback

Table 1. The survey includes the following core and open-ended items:

3. Scoring Method and Interpretation

The primary metric is the average satisfaction score across the closed-ended items. A score of 5 or higher indicates positive CRC experience and aligns with the target defined in the i-HD white paper.

The satisfaction score is defined as the percentage of respondents who select response options 5, 6, or 7 on a 7-point Likert scale. These selections represent positive user sentiment, while options 1 to 3 indicate dissatisfaction. Option 4 is interpreted as neutral, and option 5 marks the lower boundary of favourable experience.

This score complements the average (mean) by focusing on the distribution of high satisfaction, rather than central tendency alone. It provides a more intuitive, interpretable view of how many

users are truly satisfied, and is especially useful when comparing across systems, studies, or timepoints. A higher satisfaction score reflects not only system acceptance, but also consistency in positive experience across CRCs. It serves as a practical benchmark for usability, training adequacy, and overall system benefit from the site perspective.

This method aligns with previous CRC feedback tools such as the CTDataHub survey, enabling comparability across sponsors and implementations.

- This metric provides an alternative to using the average score, highlighting the proportion of users who report genuinely favourable experiences.
- It offers a clearer, more intuitive interpretation of satisfaction levels than mean values alone.
- A higher satisfaction score reflects broader and more consistent positive sentiment across respondents.

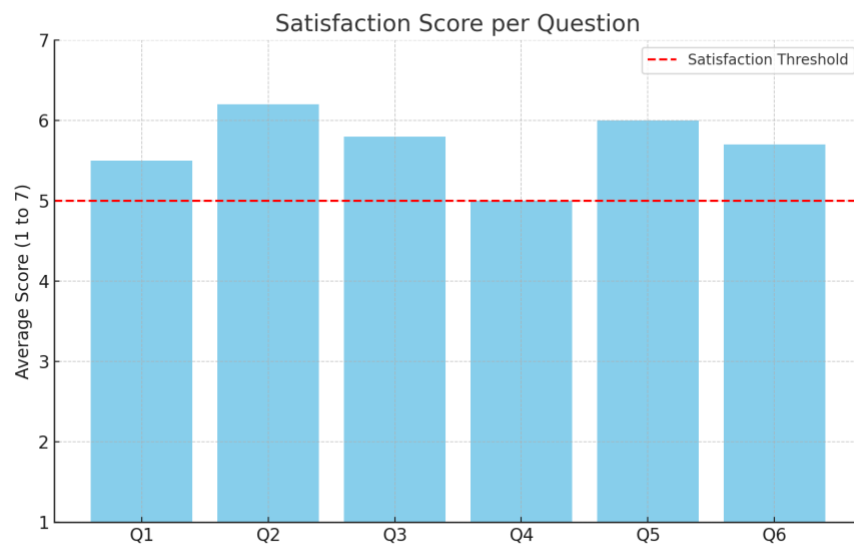


Figure 1. Satisfaction Score Calculation Example

Each item is scored 1 to 7. Compute the mean across the 6 closed items. **Example: Q1: 6, Q2: 6, Q3: 5, Q4: 5, Q5: 6, Q6: 4 – gives a Satisfaction Score = $(6+6+5+5+6+4)/6 = 5.33$** (Note: shown here with 6 items for illustration.)

Possible three secondary metrics can enhance interpretation:

- Percentage of responses scoring ≥ 6 reflects strong satisfaction and system endorsement.
- Reported time savings validate whether eSource technology meets expectations in reducing site burden.
- Correlating satisfaction with usage frequency helps reveal behavioural adoption patterns, indicating trust or potential barriers.

A standardized satisfaction metric enables evidence-based decisions on system improvements, training, and investments. Sponsors and vendors can compare outcomes across implementations, ensuring transparency and facilitating cross-study learning. Sites can benchmark their experience against peers, and regulators or networks can use the data to validate the scalability of eSource adoption.

Importantly, when multiple stakeholders use the same method, aggregate results become a valuable dataset for guiding future enhancements and innovations in digital trial infrastructure.

4. Optional Metrics for Deeper Insight

In addition to core satisfaction items, optional metrics can offer a deeper view of real-world eSource performance. Key areas may include **clarity of data transfer feedback**—whether successful transfers are clearly visible; **ease of identifying transfer failures**—detecting missing or incomplete data; **confidence in audit trail transparency**—trust in data history and traceability; and **support responsiveness**—how effectively technical issues are addressed. These metrics enrich understanding of system usability, trust, and operational fit, helping sponsors and vendors optimize solutions, improve CRC support, and drive scalable, sustainable adoption across trials and sites.

5. Annex 1- CRC Satisfaction survey for eSource-Enabled Trials

Thank you for participating in this anonymous survey!

For each statement below, please indicate your level of agreement. You may leave **questions 10 and 11** blank if they are not applicable to your experience.

1. The eSource data transfer workflow was easy for me to learn.

1	2	3	4	5	6	7
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Strongly disagree Strongly agree

2. It is easy to transfer data to the EDC using the eSource system.

1	2	3	4	5	6	7
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Strongly disagree Strongly agree

3. The eSource software correctly retrieves patient data (e.g., labs & vital signs, name, DOB).

1	2	3	4	5	6	7
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Strongly disagree Strongly agree

4. I know which lab tests and/or vital signs are transferrable via the eSource system for my study.

1	2	3	4	5	6	7
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Strongly disagree Strongly agree

5. I have received fewer queries from the sponsor/site monitor since using the eSource system.

1	2	3	4	5	6	7
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Strongly disagree Strongly agree

6. Transferring data through the eSource system is less time-consuming than manual entry.

1	2	3	4	5	6	7
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Strongly disagree

Strongly agree

7. Transferring data through the eSource system is more efficient than manual data entry.

1	2	3	4	5	6	7
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Strongly disagree

Strongly agree

8. I prefer transferring data electronically using the eSource system over manual entry.

1	2	3	4	5	6	7
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Strongly disagree

Strongly agree

9. My overall job satisfaction has increased since using the eSource system.

1	2	3	4	5	6	7
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Strongly disagree

Strongly agree

10. What challenges or difficulties have you experienced with transferring data electronically?

[Free text]

11. Do you have any additional feedback to help us improve?

[Free text]