Selected KPIs for eSource enabled trials

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

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The European Institute for Innovation through Health Data

Preface

The European Institute for Innovation through Health Data (i~HD) has launched the eSource Scale Up Task Force, to transform clinical trial data collection. This Task Force, composed of industry leaders, healthcare professionals, and technology experts, is working toward the global adoption of eSource technology to streamline clinical trial execution. Building on initiatives such as EHR4CR, EHR2EDC and EU-PEARL, the Task Force focuses on developing impartial and evidence-based recommendations for vendors, pharmaceutical companies, and healthcare institutions.

The first Deliverable, D1:Early Adopters' Minimum Criteria for Success, provides guidance on requirements or enablers for eSource. This document, **D2**: **Selected KPIs for eSource enabled trials**, is the second deliverable in a series aimed at guiding stakeholders in scaling eSource technology

Future deliverables, including **D3: The eSource Playbook** and **Guiding Principles for Preparing, Planning, Setup, and Execution of eSource Implementations**, will build on these recommendations. These resources will incorporate insights from Task Force workshops, webinars, and collaborations with hospitals, sponsors, vendors, and regulatory bodies, further refining strategies for successful eSource adoption.

This deliverable is the result of extensive discussions, analyses, and collaborative workshops involving representatives from leading organizations such as Memorial Sloan Kettering Cancer Center, University Hospitals of Cambridge, University Hospital of Essen, AstraZeneca, Johnson & Johnson, Regeneron, Sanofi, and i~HD. It offers a practical framework for assessing eSource performance, aimed at facilitating joint presentations, publications, and individual sponsor evaluations. Ultimately, it seeks to foster efficient, consistent, and scalable eSource implementations across diverse clinical environments, advancing the field of clinical research and enabling faster delivery of innovative treatments to patients.

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1 Executive Summary

EHR-to-EDC, or EHR as **eSource,** is a transformative approach that enables the direct transfer of clinical data from Electronic Health Records (EHR) into Electronic Data Capture (EDC) systems for clinical trials. Designed to reduce manual data entry, this integration securely transfers relevant patient data with consent, following quality standards to meet regulatory requirements. This technology does not replace site personnel or duplicate data capture but instead streamlines data management, significantly reducing the burden on Clinical Research Coordinators (CRCs) and accelerating study timelines.

As the second deliverable from the i~HD eSource Scale Up Task Force, this document emphasizes the importance of defining Key Performance Indicators (KPIs) to gather consistent evidence across sponsors, hospitals, vendors, and trial sites. These KPIs establish a standardized framework for evaluating eSource systems, promoting data accuracy, operational efficiency and adoption. By setting clear metrics, stakeholders can make informed decisions, drive successful eSource implementation, and build a foundation for scalable, evidence-based trials.

An initial set of 25 Key Performance Indicators (KPIs) for eSource-enabled trials was developed, covering critical aspects such as Data Quality, System Setup, Data Transfer Completeness, Cost Efficiency, HCP Engagement, and Learning Adaptability (see Appendix C). This broad set addresses operational and strategic dimensions, offering flexibility for different trial contexts. To consolidate, Task Force representatives scored the KPIs on measurability (ease of assessment) and impact (value generation), using a 10-point scale. KPIs with average scores above six for measurability and five for impact were selected. A final set of eight KPIs was agreed upon for standardization across sponsors and sites.

To assess eSource integration, the Task Force selected eight priority KPIs. These KPIs address essential dimensions like data transfer accuracy, data completeness, and time savings for site staff, forming a comprehensive evaluation framework that upholds the quality of the data flow, reduces site burden, and facilitates system integration across diverse clinical environments.

Continuous monitoring and periodic reassessment of these KPIs are recommended to ensure data quality and operational efficiency. Furthermore, some of the remaining 17 metrics (see Appendix C) can serve as secondary recommendations or requirements, adding clarity and robustness to eSource integration. These additional KPIs could cover areas like Data Security Compliance, System Flexibility, and Data Duplication, providing further guidance in achieving a well-rounded, scalable eSource framework.

Expanding the KPI framework is crucial for supporting eSource scalability in multi-site and complex trials. New KPIs such as System Uptime, Mapping Adaptability, and Data Latency Reduction could further demonstrate the system's resilience and flexibility, fostering broader adoption and enhancing eSource effectiveness in varied clinical trial landscapes.

2 Overview of KPIs for eSource enabled trials

This section provides an in-depth overview of the Key Performance Indicators (KPIs) selected for eSource-enabled clinical trials. These KPIs, identified and refined by the i~HD eSource Scale-Up Task Force, aim to establish a robust framework for evaluating the effectiveness of EHR-to-EDC data transfer processes. They represent core areas such as data quality, operational efficiency, system usability, and user engagement, essential for fostering consistent evidence-based practices across sponsors, hospitals, vendors, and trial sites.

The selected KPIs focus on measurable outcomes that enhance data accuracy, reduce manual workloads, and improve data quality across diverse clinical settings. They also serve to drive scalability by providing standardized metrics that can be applied across different studies, ensuring reliable and high-quality data transfer. By establishing these KPIs, stakeholders can assess and improve eSource integration, building confidence in its implementation and promoting its adoption across the clinical research landscape.

Table 1: Summary characteristics of eight selected eSource KPIs

No	KPI	Description	Impact	Methodology	Example of Range
1	Accuracy of Data Transfer	Ensures clinical data transfer from EHR to EDC meets or exceeds the accuracy of manual EDC entry	High priority for data integrity and reliability	Data validation tests comparing eSource with manual EDC	>98% accuracy rate; <2% error rate
2	Completeness of Data Transfer	Ensures complete transfer of all mapped clinical data from EHR to the study database	Essential for preventing data quality issues	Completeness audits and data transfer log reviews	100% completeness; explanations required for deviations
3	Source Data Verification (SDV) Reduction	Reduces time and resources needed for SDV by sponsors	High impact on sponsor cost reduction and operational efficiency	Compare SDV time and resource usage of eSource site and traditional site of the same trial	≥30% reduction in SDV time on forms that are eSource enabled
4	Improved Site Operational Efficiency	Achieves time savings for site personnel across data domains	Improves efficiency and reduces operational burden	Track data entry time pre- and post-eSource implementation	≥25% reduction in data entry time
5	User-Friendly CRC Experience & Reduced Site Burden	Measures CRC satisfaction with eSource usability and perceived workload reduction	High satisfaction indicates system adoption and reduced burden	Satisfaction surveys and CRC feedback analysis	≥5 average satisfaction on a 7-point Likert scale
6	Mapping Reusability	Achieves high accuracy in initial clinical data mapping without requiring remapping	Ensures effective initial setup, reducing rework	Compare initial mapping effort and remapping frequency	≥80% reusability
7	Decreased Query Count	Reduces number of data queries per patient visit	Indicates improved data quality and reduced need for corrections	Monitor and record data queries per patient visit	≥70% fewer queries per patient visit on forms that are eSource enabled (e.g. Lab, VS)
8	Clinical Research Coordinator (CRC) Adoption	Measures regular system usage among CRCs, indicating system acceptance	Reflects successful integration of system into clinical workflows	Track system usage metrics such as login frequency and active usage	>75% of HCPs regularly using the system

2.1 Accuracy of Data Transfer

Description: The Accuracy of Data Transfer KPI is a foundational measure in the EHR-to-EDC or eSource integration, emphasizing that clinical data transferred from EHR to EDC systems must maintain or exceed the accuracy and reliability observed with manual EDC practices. This KPI ensures that automated data transfer does not introduce errors, safeguarding the precision of clinical trial data and supporting data integrity throughout the trial lifecycle.

Impact: This KPI is a high priority because it directly affects the integrity and reliability of clinical data. Ensuring accurate data transfer reduces the risk of incorrect clinical outcomes and reinforces the credibility of trial findings. By maintaining strict quality standards, this KPI builds confidence in eSource systems, promoting broader adoption across clinical sites and studies.

Methodology: The methodology for assessing Data Transfer Accuracy involves conducting targeted data validation tests, like Source Data Verification but on a smaller scale. These tests compare a sample of transferred data between EHR and EDC systems against source EHR data or eventually manually entered data in a test form to spot discrepancies. Key integrity checks, like cross-referencing records for missing or altered data, are performed to ensure accuracy. For example, a random sample of patient records can be reviewed to confirm the transferred data matches the original EHR source. Automated validation scripts may also be used to detect inconsistencies immediately, allowing quick correction before data analysis.

Evaluation and Ranges: To achieve this KPI, a >98% accuracy rate between EHR and EDC data is typically required, ensuring high fidelity in data transfer. Acceptable performance ranges may vary slightly based on the trial phase or regulatory expectations but should generally not drop below 98%. If discrepancies exceed a 2% error rate, a root cause analysis should be initiated to identify and resolve issues. Regular audits and monitoring are recommended to detect any deviations and maintain data quality throughout the trial.

Practical Example: Consider a clinical trial where laboratory results are automatically transferred from an EHR system to an EDC platform for analysis. To validate Data Transfer Accuracy, the trial team selects 3 patients across two visits and reviews 10 data values across lab and vital sign forms, yielding 60 data values. They compare each EDC-recorded value with the original EHR data, focusing on critical parameters like blood glucose and liver enzyme levels.

In this validation, the team identifies one minor discrepancy—less than 2%—due to decimal rounding differences between the EHR and EDC, slightly altering the lab results. This discrepancy highlights the importance of aligning rounding rules between systems to ensure data consistency. As a corrective action, the EDC system's protocols are updated to match the EHRs rounding standards. This example illustrates how proactive data validation can uncover and resolve discrepancies, ensuring that data in the EDC remains as accurate as the original EHR records.

2.2 Completeness of Data Transfer

Description: The Completeness of Data Transfer KPI ensures that all mapped clinical data from the EHR system is fully and accurately transferred to the EDC platform. This KPI is critical in clinical trials to prevent any loss of essential data, thereby safeguarding the integrity and comprehensiveness of the dataset for analysis.

Impact: the Completeness of Data Transfer is vital because gaps in transferred data can result in incomplete analysis, misinterpretation of clinical outcomes, and regulatory issues. Missing data—such as key lab results, medication dosages, or adverse event reports—can impact study conclusions and, in some cases, compromise patient safety. Ensuring high data completeness also reduces the need for manual data verification, streamlining the trial process and saving both time and resources.

Methodology: Assessing the Completeness of Data Transfer involves detailed cross-referencing of mapped data fields between the EHR and EDC systems. This typically includes data transfer audits, where each data field's completeness is verified against the original EHR records to confirm that all mapped data has successfully transferred. Automated data logs further support this process, tracking transfer status in real-time and flagging any missing or incomplete entries. Any identified deviations are recorded and investigated to address potential system or mapping issues.

Evaluation and Ranges: To meet the Completeness of Data Transfer KPI, a target of 100% transfer of mapped clinical data from the EHR to the EDC is established. Any deviations from this standard should be documented with a clear justification. Acceptable performance requires that all identified gaps are explained, and corrective actions are taken if recurring issues arise. For example, any completeness below 100% should trigger an investigation and adjustments to maintain consistent data flow. Minor deviations (e.g., <1%) may be acceptable if promptly addressed and rectified.

Practical Example: In a clinical trial tracking patient vital sign, the eSource transfer includes fields for heart rate, blood pressure, and temperature. During a routine audit, the trial team finds that, in 2% of patient records, temperature data is missing in the EDC system despite being present in the EHR. Upon investigation, it’s discovered that a recent software update altered the temperature field mapping, causing these values to fail in transferring correctly.

The team logs the deviation, corrects the mapping error, and rechecks the affected records to ensure that the temperature data is now fully transferred. This example illustrates the importance of regular completeness checks and shows how addressing minor deviations proactively can maintain a comprehensive and reliable dataset, upholding the Completeness of Data Transfer KPI.

2.3 Source Data Verification (SDV) reduction

Description: The Source Data Verification (SDV) Reduction KPI quantifies the decrease in time and resources required for SDV when transitioning from manual processes to eSource integration. Traditionally, SDV demands significant manual verification to ensure that data in the EDC system matches the original source data. This KPI evaluates how effectively the eSource system automates data capture, reducing the need for manual SDV.

Impact: Reducing SDV requirements greatly enhances trial efficiency and cost-effectiveness. By minimizing manual verification, sponsors experience a lighter operational workload, allowing resources to be redirected to other critical study areas. Additionally, reducing SDV decreases overall trial costs and accelerates data analysis timelines, which not only supports regulatory compliance but also encourages the broader adoption of eSource systems across clinical research.

Methodology: This KPI is measured through a comparative analysis of SDV-related time and resources before and after eSource system implementation. Key metrics include the total hours spent on SDV, the number of personnel required, and the frequency of SDV checks per site. Detailed time-tracking and resource logs provide quantitative data on SDV effort pre- and post-eSource, highlighting where process efficiencies are gained.

Evaluation and Ranges: A successful outcome for this KPI targets a reduction of 30% or more in time and resources devoted to SDV, setting a meaningful benchmark for efficiency improvements. Any reduction below 20% may suggest limited automation benefits and prompt a review of system processes for potential optimization. Continuous monitoring ensures that SDV reductions are sustained, and any deviations from anticipated savings are investigated for further improvements.

Practical Example: In a clinical trial previously relying on manual SDV, sponsors allocated approximately 40 hours per site per month to SDV tasks. Following eSource implementation, the SDV time decreased to an average of 25 hours per month, representing a 37.5% reduction in workload. This time savings translates into considerable cost reductions and enables sponsor staff to dedicate more time to data analysis and other high-priority activities. This example illustrates how eSource systems can streamline SDV, reinforcing the KPI's focus on efficiency and cost-effectiveness. The numbers given in this example are not based on a real case.

2.4 Improved Site Operational Efficiency

Description: This KPI measures the reduction in time spent by CRC or site staff on eSource enabled data entry tasks and management tasks when using the eSource system compared to traditional methods. It aims to quantify efficiency improvements by capturing how much time is saved on routine tasks, freeing up site staff to focus more on patient care and other high-value activities.

Impact: Time savings for CRC is significant in enhancing workflow efficiency and reducing operational burden. By streamlining data transfer from EHR to EDC, the KPI alleviates repetitive tasks, minimizes data handling errors, and improves job satisfaction for healthcare providers. Time efficiencies can also reduce site costs and enhance resource allocation, ultimately contributing to a more seamless trial execution process.

Methodology: To evaluate time savings, baseline measurements of time spent on data entry tasks are gathered prior to implementing the eSource system. Once the system is active, time tracking tools are used to measure the time spent on similar tasks, allowing a comparative analysis of pre- and post-implementation time requirements. These time measurements focus on key activities such as entering patient data, handling queries, and completing documentation, and can be collected through automated logging systems or self-reported time studies by site staff.

Evaluation and Ranges: An effective range for this KPI targets a 25% or greater reduction in data entry time across eSource data domains. If time savings fall below this threshold, it may indicate inefficiencies or areas of friction in the eSource integration. Continuous monitoring of time savings helps ensure that the benefits are sustainable and allows for adjustments or additional support where needed. Any deviation from expected results can prompt a review of specific system features or site practices to identify potential improvements.

Practical Example: In a clinical trial where a CRC typically spends 40 minutes per patient visit on data entry tasks, the implementation of the eSource system reduced this time to approximately 28 minutes per visit—a 30% reduction. Staff reported that automated data transfer for lab results and medication histories was particularly beneficial, eliminating the need to manually input these details. The time saved allowed staff to allocate more attention to patient interactions and other clinical responsibilities, enhancing the trial workflow and demonstrating the practical value of the KPI for Time Savings for Site Staff. The numbers given in this example are not based on a real case.

2.5 User-Friendly CRC Experience & Perceived Reduced Site Burden

Description: The User-Friendly CRC Experience & Perceived Reduced Site Burden KPI measures how CRCs, or similar healthcare providers (HCPs), interact with and adapt to the eSource system, with an emphasis on system usability and reducing site workload. This KPI assesses how easily CRCs can navigate and utilize the system, as well as the extent to which it automates routine tasks, improving satisfaction and decreasing the need for manual data entry.

Impact: A user-friendly system that effectively lowers site burden can directly benefit the trial by promoting consistent use and minimizing data entry errors. High satisfaction among CRCs signals successful integration of the technology into their daily workflows, leading to greater adoption across trial sites and improved data quality. Additionally, a positive user experience reduces resistance to new technology, supporting the scalability and broader adoption of eSource systems.

Methodology: This KPI is assessed through structured satisfaction surveys using a seven-point Likert scale, where 1 represents "*Not at all*" and 7 represents "*To the highest extent*." This scale accurately captures CRC satisfaction, focusing on aspects like system ease of use, perceived time savings, and workload reduction. CRCs surveyed should already be well familiar with the eSource approach. Validated for precision, this scale provides granular insights into CRC experiences compared to simpler measures. In addition to survey data, metrics such as login frequency and session duration provide supplementary insights into system engagement.

Evaluation and Ranges: A successful outcome for this KPI targets an average score of 5 or higher on the Likert scale, or >80% satisfaction score (see Appendix B, reflecting general satisfaction and ease of use among CRCs. Scores between 4 and 5 indicate moderate satisfaction, suggesting potential areas for system improvement, while scores below 4 identify areas needing significant refinement. Additionally, a 25% or more reduction in time spent on data entry tasks supports a reduced site burden, measured by tracking task completion times before and after system implementation.

Practical Example: In a clinical trial using the eSource system, CRCs were surveyed after implementation, and the results showed an average satisfaction score of 6 on the Likert scale, indicating strong ease of use and substantial time savings. Many CRCs noted that auto-populated fields for vital signs significantly reduced their data entry time, supporting the KPI goal of reducing site burden. However, some users encountered challenges with certain navigation features, leading to targeted training sessions and changes to the user interface of the solution. This example illustrates how satisfaction scoring helps identify areas for usability improvements and enhances overall system adoption by reducing site burden.

Supporting reference: Sundgren et al. (2023). "eSource Interoperability Between EHR and EDC" - Evidence from a Phase III cancer trial points to notable advances in data-transfer tech." *Applied Clinical Trials". July/August issue: 20-23.*

2.6 Mapping Reusability

Description: The Mapping Reusability KPI assesses the accuracy and durability of initial data mapping from EHR to EDC, aiming to minimize the need for remapping for additional trials. High mapping reusability ensures that data alignment is both efficient and correct from the start, reducing disruptions and preventing the need for repeated data adjustments, which saves time and resources.

Impact: Effective initial mapping is crucial for a seamless data transfer process, as it reduces rework and ensures smooth data flow and is key for scaling. High mapping reusability supports a stable and accurate structure, allowing eSource transfers to proceed without frequent adjustments. This improves overall workflow, reduces site burden, and promotes consistent data requirements across studies, ultimately lowering operational costs and enhancing trial efficiency.

Methodology: Mapping reusability is measured by tracking the accuracy of initial data mapping and the frequency of remapping requests post-implementation. Key metrics include the percentage of data accurately mapped initially and the scope of remapping required over time. Efficient mapping is reflected by high initial accuracy with minimal need for subsequent adjustments, ensuring reliable data flow from the beginning.

Evaluation and Ranges: Successful KPI attainment is defined by achieving over 80% reusability in initial data mapping, with minimal remapping required throughout the trial and following trials. Performance below this threshold may signal issues with the initial setup, suggesting a need for system optimization. Ideally, remapping frequency should remain under 5%, allowing for consistent and reliable data flow without significant disruption.

Practical Example: In a clinical trial where patient data on vital signs and lab results is mapped from EHR to EDC, initial mapping accuracy is closely monitored. During the setting up of the next study, the team observes a mapping reusability of 80%, with only 3% of records requiring minor remapping due to differences in lab requirements. Adjustments to the mapping configuration are implemented, eliminating the need for further remapping. This example demonstrates how high initial mapping reusability reduces site workload, supports resource efficiency, and aligns with the KPI's goal of maximizing setup accuracy and minimizing rework. The numbers given in this example are not based on a real case.

2.7 Decreased Query Count

Description: The Decreased Query Count KPI measures improvements in data flow by tracking the reduction in the number of data queries per patient visit. High-quality data transfer from EHR to EDC reduces the potential for errors, inconsistencies, or missing information, which in turn decreases the number of queries and corrections needed throughout the trial.

Impact: A reduction in data queries positively impacts trial efficiency and data accuracy. Fewer queries mean less time and resources spent on data correction, leading to lower operational costs and faster data analysis and higher satisfaction of CRC. This KPI serves as an indicator of effective data management processes and quality improvements within the eSource integration, resulting in more reliable and accessible clinical data.

Methodology: This KPI is assessed by tracking and recording the number of data queries issued per patient visit over time for *eSource-enabled forms* (e.g., Lab, Vital Signs). Comparisons of the average query count before and after EHR-to-EDC implementation reveal improvements in data quality. Query logs within the EDC system provide detailed data on query counts, supporting continuous monitoring and analysis to pinpoint specific areas requiring further attention or enhancement.

Evaluation and Ranges: A successful outcome for this KPI is defined by achieving a reduction of ≥75% in queries per patient visit *on eSource-enabled forms*. Meeting or surpassing this target indicates effective improvement in data quality and process efficiency. If the reduction falls below this threshold, it may highlight areas needing further refinement within the data transfer or EHR mapping processes.

Practical Example: In a clinical trial with an initial query rate of seven queries per patient visit due to frequent data discrepancies, the integration of an eSource system significantly improves data accuracy. After implementation, the average query count drops to two per patient visit, achieving a reduction of five queries, or approximately 71%. This reduction illustrates how the eSource system minimizes inconsistencies, enhances data quality, and decreases the time required for data reconciliation, effectively meeting the KPI goal for Decreased Query Count. The numbers given in this example are not based on a real case.

2.8 Clinical Research Coordinator Adoption

Description: The Clinical Research Coordinator (CRC) Engagement KPI measures the extent of CRC, or healthcare provider (HCP) interaction, with the eSource system, indicating the system's acceptance and integration into daily clinical workflows. High adoption reflects that CRCs find value in the system, feel comfortable using it, and regard it as an essential part of their data management responsibilities within the trial.

Impact: High adoption among CRCs is essential for the success and sustainability of the eSource system, as it signifies that the system is well-integrated and readily accepted. Consistent CRC adoption enhances data quality and reliability, ensures timely data entries, and minimizes errors associated with manual data handling. Strong adoption also promotes compliance, fosters a positive attitude toward the system, and supports scalability across multiple sites, which is crucial for broader EHR-to-EDC adoption.

Methodology: This KPI is only useful in institutions that already have multiple studies eSource. Adoption levels are monitored through system usage metrics, including login frequency, session durations, and the frequency of specific data entry tasks. Regular monitoring of user login rates helps assess the percentage of active CRC users. Additionally, periodic usage analytics can reveal patterns of underuse or identify areas where CRCs may require additional training or support. This tracking is typically conducted over a defined timeframe to establish adoption consistency and assess long-term system integration.

Evaluation and Ranges: An adoption target of more than 75% of CRCs regularly using the eSource system signifies effective acceptance and integration. Consistent usage above this threshold indicates that CRCs perceive the system as valuable and have incorporated it into their daily workflows. Depending on the implementation process at an investigational site Engagement below 75% may suggest potential barriers to system adoption, necessitating additional training, user support, or enhancements in usability.

Practical Example: In an HCO utilizing the eSource system, adoption metrics reveal that 80% of CRCs working on eSource enabled trials log into the system weekly to enter or review data, meeting the KPI target. This consistent login frequency shows that CRCs actively integrate the system into their routines. Feedback from CRCs highlights the system's user-friendly design and streamlined data entry features as major factors driving its frequent use. However, a subset of CRCs logs in less frequently, prompting targeted training sessions to build confidence in system functionality. This example demonstrates how high adoption validates the system's acceptance and integration, supporting continuous use and enhancing data reliability across the trial. The numbers given in this example are not based on a real case.

3 Summary & Recommendations

The selection of eight KPIs for eSource-enabled trials establishes a foundational framework to assess and enhance the quality, efficiency, and scalability of eSource integration across diverse clinical study settings. These prioritized KPIs—Data Transfer Accuracy, Completeness of Data Transfer, Source Data Verification (SDV) Reduction, Time Savings for Site Staff, User-Friendly CRC Experience, Mapping Reusability, Decreased Query Count, and CRC Engagement—cover critical dimensions of eSource functionality.

The *Accuracy and Completeness of Data Transfer* KPIs ensure that data from EHR systems is both precise and comprehensive, upholding clinical data integrity essential for regulatory and analytical rigor. *SDV Reduction* reflects efficiency improvements by reducing the need for manual data verification, thus freeing sponsor resources for other study priorities. *Time Savings for Site Staff* and *User-Friendly CRC Experience* focus on reducing the operational burden and improving usability, which is vital for fostering site-level adoption. *Mapping Reusability* minimizes rework by optimizing initial mapping setups, while *Decreased Query Count* reduces data discrepancies and corrections, contributing to cost-effective data management. Finally, *CRC Adoption* serves as an indicator of system acceptance and seamless integration into daily workflows, supporting the sustainability of eSource technology.

Recommendations: While these eight KPIs form the core metrics for evaluating eSource success, some of the remaining 17 metrics initially developed could provide additional value and clarity for eSource integration. These supplementary KPIs can function as recommendations or requirements to support specific aspects of EHR-to-EDC setups, enabling a more nuanced approach to implementation. For example, these additional KPIs can serve to measure aspects like *Data Security Compliance* or *System Customization Flexibility*, addressing concerns related to regulatory compliance and site-specific needs, which can further guide stakeholders in achieving a robust eSource framework. To strengthen these KPIs, continuous monitoring and feedback mechanisms are recommended, allowing sites and sponsors to collaboratively address any deviations or improvement areas. Benchmarking each KPI and setting clear corrective action thresholds will reinforce accountability and data quality.

Outlook for Including New KPIs for Scalability: Expanding the KPI framework with additional metrics will play a crucial role in enhancing the scalability of eSource systems across diverse clinical settings. Potential new KPIs include *System Uptime*, which measures the reliability and availability of the technology in large-scale, multi-site trials, ensuring uninterrupted data access. Another valuable addition is *Mapping Adaptability*, which tracks the system's ability to integrate evolving data elements without causing disruptions, a key factor in supporting complex study protocols. Additionally, *Data Duplication Reduction* can monitor and minimize redundancies between EHR and EDC systems, ensuring streamlined data management and higher efficiency. *Sponsor Adoption,* which means sponsor's reliance on this capability in all their trials in eSource enabled sites and *Data Coverage*, which means scaling beyond the initial structured data domains.

Integrating these supplementary KPIs will strengthen the adaptability and resilience of eSource systems, demonstrating their effectiveness in managing increasingly complex and high-demand clinical trials. By applying these KPIs consistently across trials, sites, vendors, and sponsors, stakeholders can facilitate better information sharing and evidence generation. This collaborative approach will support a more robust framework for scaling up eSource-enabled trials, ultimately driving broader adoption and enhancing clinical research efficiency.

4 Appendix A: Methodology of selection

An initial broad set of 25 Key Performance Indicators (KPIs) or success criteria for eSource-enabled trials was developed, incorporating the six criteria already utilized in previous eSource-supported trials (see Appendix C). This approach ensures comprehensive coverage of critical aspects such as **Data Quality**, **System Setup**, **Data Transfer Completeness**, **Cost Efficiency**, **HCP Engagement**, and **Mapping Learning & Adaptability**.

The rationale for selecting this broad set is to address the multifaceted challenges and opportunities in eSource-enabled trials. By including diverse criteria, the framework captures both operational and strategic dimensions, enabling a holistic evaluation of trial performance. The expanded list allows for flexibility in tailoring KPIs to specific trial contexts while drawing insights from recent literature and industry benchmarks.

The ranking of these KPIs is subjective, reflecting expert judgment informed by current references and practical experience. This iterative process ensures the proposed KPIs remain relevant, actionable, and aligned with the evolving needs of eSource trials.

A proposal for the eSource Task Force is to reduce, revise, consolidate, and agree on a set of top 8-10 criteria to be used across sponsors and sites. This consolidated list would serve as an excellent deliverable, from the Task Force. Moreover, an agreed set of success or assessment criteria will facilitate joint presentations and publications and improve individual sponsor evaluations of eSource systems.

Methodology of selection: 15 Task Force representatives across member organisations scored all 25 KPIs towards two aspects; measurability, or how easy it is to assess a KPI. The second aspect was around the impact, or which value generation it has on the clinical trial, sponsor or site staff. Both aspects were scored against a 10-grade scale, number 1 (low) and 10 (high).

The final set of 8 KPIs were selected were those who achieved an average score of above six for measurability, and above five for impact. After a joint review a final set of eight KPIs were selected.

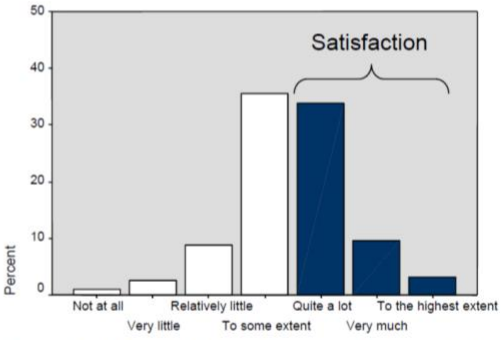
5 Appendix B: Examples of Items for "User-Friendly HCP Experience"

Item no.	Items	Assessed aspect
1	To what extent do you find the "eSource service provider" system easy to use?	Usability
2	To what extent does the "eSource service provider" technology enable faster transfer of study data compared to standard methods?	Time saving
3	To what extent do you feel the training provided for using "eSource service provider" technology was adequate for performing the trial?	Adequate Training
4	To what extent do you believe that the "eSource service provider" reduces site burden by semi-automating data transfer during trials?	Reduce Site Burden
5	To what extent do you think the "eSource service provider" reduces data entry errors compared to current manual processes?	Reducing Errors
6	To what extent do you believe the "eSource service provider" can expand beyond the data elements used in the pilot (local lab, con med, and vital signs)?	Effectiveness

Response options: (1) Not at all, (2) Very little, (3) Relatively little, (4) To some extent, (5) Quite a lot, (6) Very much, (7) To the highest extent.

Satisfaction analysis

- Satisfaction analysis is an alternative way to describe results other than the average of response options between 1 and 7
- *"Satisfaction score"* refers to the portion of respondents who either have answered to response options 5, 6 & 7 for a certain item (e.g. "Quite a lot", "Very much" or "To the highest extent")
- This measure is chosen to simplify meaning and interpretation
- Higher satisfaction score means simply a better condition with higher resolution in responses (compared to mean values)



Example - "To what degree do you experience that usability in current Information infrastructure is satisfactory?" – Satisfaction score is 46%

6 Appendix C: Original 25 KPIs for eSource Trials

Exploration of new eSource KPIs – eSource Task Force
/Mats Sundgren July-15, 2024

The objective is to expand and rank the most relevant KPIs for EHR-to-EDC/eSource implementation and execution, beyond the initial six criteria published in **eSource Interoperability Between EHR and EDC** (ACT 2023). These original criteria are marked with an **[*]** in the table.

An initial broad set of 25 success criteria, including the six criteria, have been proposed. These criteria emphasize critical aspects such as Data Quality, System setup, Data Transfer Completeness, Cost Efficiency, HCP Engagement and Mapping Learning & Adaptability. The ranking is subjective and partly based on recent literature references.

A proposal for the eSource Task Force is to reduce, revise, consolidate, and agree on a set of top 10-15 criteria to be used across sponsors and sites. This consolidated list would serve as an excellent deliverable, from the Task Force. Moreover, an agreed set of success or assessment criteria will facilitate joint presentations and publications and improve individual sponsor evaluations of eSource systems.

Rank No	Evaluation Criteria	Success Criteria	Importance	Methodology	Rationale for Ranking
1 [*]	Data Quality & Accuracy	EHR-to-EDC system transfer of clinical data is equal to or better than traditional practice (manual EDC)	Ensures reliable data transfer	Perform data validation tests comparing EHR-to-EDC transfers with manual EDC transfers.	High priority as it directly affects the reliability and integrity of clinical data.
2 [*]	Technology Setup, Execution & Training	YES/NO of establishing a stable end-to-end EHR-to-EDC service throughout the pilot with complemented training of site staff	Fundamental to system operability	Conduct pilot testing, assess system stability, and verify training completion with feedback surveys.	Fundamental to ensure the system is operational and staff are well-prepared, forming the basis for success. [
3 [*]	Data Transfer Completeness	Ability to transfer 100% of mapped clinical data from EHR to study database. Any deviation should be explained	Ensures all necessary data is transferred	Check data transfer logs and perform completeness audits on mapped data fields.	Essential to ensure no critical data is missed during transfer, impacting overall data quality.
4	Impact on Source Data Verification	Significant reduction in the time and resources needed for Source Data Verification by sponsors	Reduces sponsor workload and cost	Measure the time and resources spent on Source Data Verification before and after EHR-to-EDC implementation.	High impact on reducing sponsor costs and improving efficiency, a major benefit of EHR-to-EDC integration.
5	Patient Data Security	No data breaches or security incidents in the EHR-to-EDC data transfer process	Ensures compliance and data protection	Perform regular security audits and monitor for any incidents.	Vital for compliance and maintaining trust, given the sensitive nature of clinical data.

6	Regulatory Compliance	100% compliance with relevant regulations and guidelines for EHR-to-EDC data transfer	Ensures legal and ethical standards	Conduct compliance audits and ensure all protocols meet regulatory standards.	Ensures the legal and ethical conduct of clinical trials, avoiding potential legal issues.
7	Training Effectiveness	90% or higher of site staff passing a post-training assessment on EHR-to-EDC processes	Ensures staff are well-prepared	Administer post-training assessments and track pass rates.	Ensures that staff are fully capable of using the system effectively, reducing errors and increasing efficiency.
8	Data Fidelity	0% translation & transcription errors in the EHR-to-EDC data transfer process	Ensures data accuracy and integrity	Conduct regular audits and error checks on data transfers.	Critical to maintain the accuracy and integrity of transferred data, preventing potential errors.
9	Data Mapping Accuracy	Less than 5% deviation in data mapping accuracy between EHR and EDC systems	Ensures accurate data alignment	Conduct regular audits of data mapping accuracy.	Ensures that the data mapped from EHR to EDC is accurate, reducing discrepancies.
10 [*]	Time Savings for Site Staff	More than 25% time savings of site personnel (on average) across all three data domains	Reduces operational burden and improves efficiency	Measure time spent on data entry before and after implementation using time-tracking tools.	Significant time savings for site staff enhances efficiency and reduces operational burden.
11	Data Latency	Difference in time from patient visit to data entry in EDC versus baseline. At least 15 days reduction	Reduces delays in data availability	Track and compare data entry timestamps in EHR and EDC systems.	Reducing data latency improves the timeliness of data availability for analysis and decision-making.
12 [*]	Data Availability in EHR	Average of more than 50% of target mapped fields exist for selected clinical data domains in the EHR	Ensures data presence for transfer	Audit EHR records to confirm the presence of target data fields.	Ensures that the necessary data is available for transfer, impacting the completeness of the dataset.
13 [*]	User-Friendly HCP Experience & Perceived Reduced Site Burden	More than 80% satisfaction score from healthcare provider (HCP) staff regarding EHR-to-EDC software (seven Likert scale)	High user satisfaction indicates success	Conduct user satisfaction surveys and analyze feedback from HCP staff.	High user satisfaction indicates the system is well-received, reducing site burden and increasing adoption.
14	Mapping Efficiency	Achieve more than 90% accuracy in initial clinical data mapping without requiring remapping	Ensures effective initial setup and reduces rework	Compare initial mapping accuracy and frequency of remapping requests.	Reduces the need for remapping, saving time and resources.
15	Cost Efficiency	Reduction in overall costs by at least XX% (e.g. 15-20%) post EHR-to-EDC implementation	Demonstrates financial benefits	Analyze and compare costs before and after implementation.	Demonstrates financial benefits, making the system more attractive to stakeholders.
16	Scalability	Successful scalability of EHR-to-EDC system to additional sites without major issues	Ensures system can be expanded	Track and evaluate the performance and issues during the expansion to new sites.	Ensures the system can be effectively expanded to more sites, supporting broader implementation.
17	HCP Engagement	More than 75% of HCPs regularly using the EHR-to-EDC system	Reflects system acceptance and integration	Track system usage metrics and user login frequencies.	High engagement indicates acceptance and integration of the system into regular workflows.
18	Mapping Adaptability	Ability to quickly adapt and map new clinical data fields as study requirements evolve	Ensures flexibility and responsiveness to changes	Track the time taken to incorporate new data fields into the mapping process.	Ensures the system can quickly adapt to new requirements, maintaining flexibility.

19	Mapping Learning & Adaptability	Improved mapping accuracy and efficiency over time by leveraging previous mappings across studies	Ensures continuous improvement and learning	Track mapping performance over multiple studies and incorporate feedback to refine mapping processes.	Continuous improvement through learning enhances overall mapping efficiency and accuracy.
20	System Uptime	99.9% system uptime for EHR-to-EDC software during the pilot period	Ensures system reliability	Monitor system uptime logs and report any downtime incidents.	High system uptime is crucial for uninterrupted data transfer and reliability.
21	Decreased Query Count	At least 2.5 reduction of the number of data queries per patient per visit	Indicates improved data quality	Monitor and record the number of data queries per patient visit.	Fewer data queries indicate higher data quality and reduced need for corrections.
22	Decreased Monitoring Productivity	A 20% reduction of monitoring visits	Reflects reduced workload and cost savings	Track the number of monitoring visits and compare with baseline data.	Reducing monitoring visits lowers costs and workload for both sites and sponsors.
23	Mapping Efficiency Feedback	More than 85% positive feedback from site staff on mapping efficiency and ease of use	Reflects user satisfaction with the mapping process	Conduct feedback surveys and analyze responses related to mapping efficiency.	Positive feedback from site staff ensures the mapping process is user-friendly and efficient.
24	Reduction in Data Duplication	Decrease in the percentage of data points duplicated between research systems and EHRs	Reduces redundancy and cost	Measure the percentage of data points duplicated pre and post EHR-to-EDC implementation.	Reducing data duplication decreases redundancy and associated costs.
25	Mapping Standardization	Consistent use of standardized mapping elements across studies to improve efficiency and accuracy	Ensures uniformity and reduces variability	Develop and implement standardized mapping protocols and regularly review for adherence and improvement.	Standardized mapping protocols enhance consistency and efficiency across studies.