

Annual Report 2024-2025

i-HD eSource Scale Up Task Force

July 18th, 2025



eSource

Scale Up Task Force

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Preface

The eSource Scale-Up Task Force, coordinated by the [European Institute for Innovation through Health Data \(i~HD\)](#), was established in 2024 to accelerate the digital transformation of clinical trial data collection. In just over a year, the Task Force has grown into a dynamic network of healthcare institutions, pharmaceutical sponsors, united by a shared vision: to reduce redundancy, increase data quality, and scale EHR-to-EDC (eSource) technologies globally.

In its *pre-competitive phase*, the Task Force brings together leading pharma sponsors and academic hospitals stakeholders to co-create foundational tools and frameworks for EHR-to-EDC integration. Operating within this non-commercial, shared-value environment—influenced of EFPIA’s “[Partners in Research](#)” initiative—competing organizations unite to solve common challenges without compromising individual pipelines.

This spirit of collaboration enables the Task Force to focus on implementation, not rivalry. Harnessing collective insight, the group translates global standards (e.g., FHIR, CDISC) into *pilot-ready outputs*—such as readiness criteria, KPI tools, satisfaction surveys, and governance guidance—ensuring the outputs are operational and repeatable across diverse institutions.

This Annual Report covers activities and accomplishments from **June 2024 to June 2025**. It highlights progress across strategic deliverables, including four white papers, multiple conference presentations, peer-reviewed publications, and the formation of dedicated Reference Groups for both sites and sponsors.

1 Executive Summary

Throughout 2024 and Q2 2025, the eSource Scale-Up Task Force—coordinated by i~HD—advanced its mission to accelerate EHR-to-EDC integration by delivering **practical, pilot-ready tools**. Unlike other eSource initiatives (e.g., TransCelerate, HL7 Vulcan, CDISC), which focus on standards, interoperability, or data modelling, this Task Force is unique for its **hospital-and-sponsor-led co-creation with an operational focus**—not parallel workstreams.

Core members include AstraZeneca, Johnson & Johnson, Sanofi, Regeneron, Lilly, Memorial Sloan Kettering (MSK), Cambridge University Hospitals (CUH), University Hospital of Essen, and Mayo Clinic. These organizations contributed to key deliverables, including readiness criteria, KPI frameworks, implementation guidance, and the evolving eSource Playbook.

In 2025, the Task Force launched Reference Groups for both sites and sponsors. The Site Reference Group is in dialogue with over a dozen hospitals, with University Hospital of Heidelberg (Germany) and IRST (Italy) confirmed. The Sponsor Reference Group is in structured discussions with more than five pharmaceutical companies.

Key achievements include:

- Publication of white papers on readiness criteria (D1), eSource KPIs (D2), and the eSource Playbook (D3)
- Release of the first Playbook Annex on data flow and integration models
- Development of a standardized CRC Satisfaction Survey to benchmark user experience (KPI #7)
- Over a dozen conference presentations and three publications
- Announcement of the inaugural International eSource Conference as part of i-HD Annual Conference (December 2–5, 2025, Ghent)

Looking ahead to Q3 2025 and Q2 2026, the Task Force will focus on operational scale-up through six coordinated workstreams. Key priorities include:

- Launching the Technical Vendor Reference Group in Q3 to engage middleware, EHR platforms, and integration tool developers
- Expanding the Site Reference Network to 40 hospitals, including 10 “premium” digitally mature sites
- Publishing additional Playbook annexes on value demonstration, contracting, therapeutic area innovations, CRF design, and data scopes
- Scaling KPI deployment and launching the eSource Evidence Repository for centralized impact benchmarking
- Deploying the eSource Site Maturity Assessment Tool for structured onboarding and institutional self-evaluation

Supported by ongoing sponsor engagement and structured implementation guidance, these efforts reinforce the Task Force’s unique role in operationalizing eSource at scale—delivering real-world outcomes faster and more collaboratively than any single institution or initiative.

2 About the eSource Scale-Up Task Force

Launched in early 2024 by the European Institute for Innovation through Health Data (i~HD), the [eSource Scale-Up Task Force](#) is a collaborative initiative designed to modernize and streamline the execution of clinical trials. The Task Force brings together sponsors, hospitals, to scale the use of EHR-to-EDC data transfer solutions.

Its core mission is to reduce site burden, improve data quality, and promote system interoperability through vendor-neutral, evidence-based frameworks. The initiative builds on EU-funded efforts such as [EHR4CR](#), [EHR2EDC](#), and [EU-PEARL](#).

Founding members include AstraZeneca, Johnson & Johnson, Sanofi, Regeneron, Memorial Sloan Kettering Cancer Center (MSK), Cambridge University Hospitals (CUH), University Hospital of Essen and i~HD. In 2025, Lilly and Mayo Clinic joined the initiative.

Two dedicated Reference Groups were also initiated in 2025:

- The **Site Reference Group**, comprising early adopters and potential new members, includes: University Hospital of Heidelberg (Germany) and Istituto Romagnolo per lo Studio dei Tumori (IRST) (Italy) (confirmed), Sahlgrenska University Hospital (Sweden), Karolinska University Hospital (Poland), GEMELLI (Italy), 12 de Octubre University Hospital and Vall d'Hebron University Hospital (Spain), Institut Gustave Roussy and University Hospital of Nantes (France), Charité Universitätsmedizin Berlin, University Hospital of Frankfurt, and Hannover Medical School (MHH) (Germany) on-going discussion
- The **Sponsor Reference Group** includes industry leaders with ongoing discussions involving MSD, Bayer, Pfizer, Roche, and Novartis.
- **Technical Vendor Reference Group** (*launching Q3 2025*): Will convene representatives from EHR vendors, EDC platform providers, middleware/EHR2EDC developers, and systems integrators. This group is critical to ensure that real-world digital infrastructure aligns with Task Force deliverables and scales effectively across different technical ecosystems.
- The overarching aim is to engage **up to 40 hospitals interested in eSource implementations**, with the Technical Vendor group enhancing communication, technical alignment, and validation of Task Force outputs through 2025–2026.

3 Strategic Framework and Progress

3.1 From Vision to Scale-Up: Rationale for eSource and the problem it addresses

Clinical trial workflows are increasingly constrained by the manual extraction and re-entry of data from hospital Electronic Health Records (EHRs) into sponsor-owned Electronic Data Capture (EDC) systems. In oncology trials in particular, this duplication affects more than 50% of data points and contributes to up to 20% of study costs. The growing complexity of data (e.g., genomics, imaging, and real-world sources) further amplifies site burden, data error rates, and regulatory risk.

eSource—defined as the automated, regulatory-compliant transfer of structured clinical data from EHR to EDC—offers a transformative path forward. The taskforce recommended eSource approach aligns with global interoperability standards (HL7® FHIR®) and global terminological standards such as LOINC and SNOMED, reduces manual effort, increases traceability, and supports near real-time access to trial data.

Despite its potential, eSource adoption remains uneven due to fragmented infrastructure, inconsistent guidance, and insufficient implementation experience. The Task Force was created to address these barriers through coordinated action, peer learning, and public evidence.

3.2 Strategic Deliverables and Milestones

Between June 2024 and June 2025, the Task Force held **five two-day workshops** that played a central role in shaping deliverables and fostering consensus. These included in-person meetings in **Brussels** (hosted by Johnson & Johnson), **Gothenburg** (hosted by AstraZeneca), **Paris** (hosted by Sanofi), and **Uxbridge** (hosted by Regeneron), as well as a full virtual workshop led by Johnson & Johnson. These sessions enabled deep technical alignment, peer validation, and cross-functional input into the development of the KPI framework, Playbook, and early adopters' minimum criteria for success.

In addition to the workshops, the Task Force met virtually on a weekly basis throughout 2024–2025 to review deliverables, align stakeholder input, and maintain momentum across workstreams.

The face-to-face meetings in particular were instrumental in building trust across stakeholders and accelerating co-development. The Task Force's 2024–2025 roadmap is structured around four key deliverables:

- **D1. Early Adopters' Minimum Criteria for Success.** Defines essential technical, operational, and governance conditions for trial sites to implement eSource.
- **D2. Selected KPIs for eSource-Enabled Trials.** A harmonized performance framework to evaluate benefits, track implementation progress, and benchmark across institutions.

A fourth deliverable, developed in 2025, expands on *KPI #5 – [User-Friendly CRC Experience and Perceived Reduced Site Burden](#)*. This detailed methodology provides a standardized satisfaction survey for Clinical Research Coordinators (CRCs). The instrument uses a 7-point Likert scale to assess usability, efficiency, trust, and job satisfaction, and includes both closed and open-ended questions. It is designed to be deployed post-implementation across sites and vendors, enabling consistent benchmarking and cross-trial insights. The tool supports broader application of the KPI framework and will contribute to evidence generation as part of upcoming scale-up studies in 2026.

- **D3. eSource Playbook.** A comprehensive guidance document covering readiness planning, vendor onboarding, data flow design, continuous quality improvement (CQI), and stakeholder engagement. In 2025, a new Annex was added to detail eSource implementation patterns—offering a practical taxonomy of integration and collaboration models. The Playbook will continue to evolve, with new annexes published on a quarterly basis to address priority topics such as value demonstration, contracting models, and regulatory compliance.
- **D4. A site maturity assessment capability.** This deliverable will provide hospitals with a structured tool to self-assess eSource readiness across governance, technology, and workflow

domains. It supports consistent benchmarking, tailored onboarding, and alignment with sponsor expectations—helping sites prioritize next steps toward scalable, standards-based eSource adoption across therapeutic areas and trial phases.

These deliverables have been informed and are being validated through practical experience at member hospitals.

4 2025 Outputs and Deliverables

4.1 Research papers

In 2025, the Task Force published and submitted several influential articles that highlighted progress, validated field experiences, and promoted peer learning:

Applied Clinical Trials (Aug 2024) – “Streamlining Clinical Trials with eSource: Insights from MSK”.

This article provides a detailed account of eSource implementation at Memorial Sloan Kettering Cancer Center (MSK), offering insights into the practical, operational, and cultural dynamics of enabling EHR-to-EDC integration in a leading U.S. oncology setting.

The paper focuses on Clinical Research Coordinator (CRC) experience, emphasizing time savings, usability, and data quality improvements. It outlines how MSK navigated HL7® FHIR®-based interoperability, sponsor engagement, and vendor alignment, and provides real-world evidence of reduced transcription tasks and query rates.

The article also discusses early validation of key performance indicators (KPIs), including CRC satisfaction and interoperability readiness. Importantly, it highlights how MSK’s site-led innovation influenced the design of Task Force deliverables—particularly the Playbook and KPI framework—while providing a replicable model for other academic medical centers exploring digital-first clinical trials.

The image shows the cover of an article titled "Streamlining Clinical Trials with eSource: Insights from MSK" from Applied Clinical Trials. The cover features a header "DATA MANAGEMENT" and three author portraits: Mats Sundgren, PhD (Industry Science Director, MD), Gyneth Santiago (Clinical Research Coordinator, Memorial Sloan Kettering Cancer Center (MSK)), and Joseph Lengfellner, Sr. Director (Memorial Sloan Kettering Cancer Center (MSK)). The main text discusses the challenges of clinical trial data collection, the benefits of eSource, and the role of CRCs. It mentions that the number of data points collected in oncology trials has increased significantly, and that eSource can reduce transcription tasks and query rates. The article also highlights the importance of CRCs in ensuring data quality and regulatory compliance.

Applied Clinical Trials (Apr 2025) – “Scaling eSource Across Oncology Centers”. Co-authored by three Task Force sites and three leading U.S. institutions—**MSK, Mayo Clinic, MD Anderson, Cambridge University Hospitals (CUH), City of Hope, and University Hospital of Essen**—this multi-site article captures shared learning from eSource implementation in oncology clinical trials.

The paper presents a four-phase roadmap: readiness assessment, technical onboarding, pilot evaluation, and operational integration. It compares regulatory environments, EHR maturity, and sponsor collaboration models across institutions, offering practical insight into both common enablers and context-specific barriers.

Empirical results demonstrate consistent operational gains across all six centers. Most notably, CRC feedback and workflow analysis revealed that data entry for oncology trials can require **at least five minutes per data point**—highlighting the significant time savings offered by structured eSource workflows. Additional benefits included reduced Source Data Verification (SDV), fewer queries, and increased user confidence in EHR-derived data.

This is the first article to align real-world findings with the Task Force’s KPI framework, specifically on workflow efficiency, CRC satisfaction, and interoperability readiness. It establishes the value of shared infrastructure models and adaptable governance. The publication laid the groundwork for upcoming annexes on value demonstration and helped catalyse the expansion of Task Force Reference Groups.

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Scaling eSource-Enabled Clinical Trial Projects

The challenges, opportunities, and strategic outlook for oncology centers.

Oncology clinical trials are increasingly complex, driven by rising data volumes, regulatory requirements, and inefficiencies in manual data handling. Current trial processes require research staff to manually extract, transcribe, and validate clinical data from electronic health records (EHR) into electronic data capture (EDC) systems. These manual processes, such as data entry, consume significant time and resources. More than 50% of clinical trial data is duplicated between research systems and hospital EHRs, with around 20% of total study costs typically allocated to data duplication and verification. As oncology trials expand to incorporate genomics, biomarker imaging, and digital health data, the volume of data per patient is multiplying, intensifying site burdens, increasing costs, and slowing trial execution.^{1,2}

eSource technology offers a transformative solution by enabling automated EHR-to-EDC data transfers, eliminating redundant data entry, and improving accuracy. By seamlessly integrating structured data formats such as FHIR, HL7, SNOMED, and LOINC, eSource ensures real-time data availability, reduces errors, and enhances regulatory compliance. Additionally, artificial intelligence (AI)-powered automation is increasingly being leveraged to process unstructured data, such as physician notes, imaging, and pathology reports, further reducing site workload and improving data standardization.³

Early adopters of eSource, such as Memorial Sloan Kettering, Mayo Clinic, and MD Anderson Cancer Center, have reported significant improvements in trial efficiency. Case studies show that eSource can reduce site burden by 30%, cut transcription errors, and accelerate database lock times, ultimately shortening the time to bring new therapies to market.⁴

As oncology research centers scale eSource adoption, the field is shifting toward a fully digital, clinical trial ecosystem. The transition to real-time, interoperable data capture not only

increases efficiency, but also supports adaptive trial designs, enhances patient recruitment, and fosters a collaborative ecosystem among sponsors, technology vendors, and research institutions. eSource represents a pivotal advancement in the future of oncology trials, ensuring they are faster, more cost-effective, and data-driven.

Overview of participating oncology research centers

The six oncology centers that are part of this study represent a broad spectrum of expertise, size, and specialties, playing pivotal roles in global cancer research and care. These centers are also recognized as eSource Champion sites, actively training or preparing for eSource-enabled trials and pioneering innovations in clinical trial efficiency. Mayo Clinic Comprehensive Cancer Center (MCC), spanning three US sites, excels in translational research and conducts more than 1,500 trials annually, supported by 500+ research staff.

City of Hope National Medical Center (COH) in California emphasizes innovative oncology treatments, enrolling 5,000 patients in 730+ annual trials and digitizing workflows for efficiency. MD Anderson Cancer Center (MDACC) in Houston, Texas, one of the world's largest, has 760 inpatient beds and conducts 1,600+ trials yearly. Memorial Sloan Kettering Cancer Center (MSK) in New York, a global leader in cancer care and research, features 314 inpatient beds and currently has more than 1,300 therapeutic clinical trials open, excelling in advanced therapies and precision oncology.

The Cancer Research UK Cambridge Center, including Cambridge University Hospitals (CUH) NHS Foundation Trust, specializes in investigator-initiated trials and translational science within a university hospital, leveraging structured data integration. University Hospital of Essen (UKE) in Germany, with around 1,300 beds, is a leader in digitization, using FHIR-based data systems and

Precision Medicine Journal (Cambridge University Press, under review).

This peer-reviewed Perspective article, entitled *“Accelerating eSource Scale-Up in Oncology Clinical Trials: The i~HD Task Force Initiative”* was submitted in June 2025 to *Precision Medicine Journal*, articulates the rationale behind the formation of the i~HD eSource Scale-Up Task Force and provides the conceptual foundation for its core outputs—including the eSource Playbook and KPI framework. The article presents a scalable, vendor-neutral framework to address systemic inefficiencies in oncology trials caused by manual EHR-to-EDC workflows.

It was developed as a consensus contribution from the entire Task Force and includes over 20 co-authors from 10 organizations, representing sponsors, hospitals, coordinating bodies, and technical advisors. Drawing on multi-country implementation experience, the paper highlights barriers to scale such as fragmented infrastructure, workflow misalignment, and lack of standard performance measures.

On-going research study commissioned for Applied Clinical Trials (Nov 2025) – “Unlocking Unstructured Health Data: A New Frontier for eSource-Enabled Clinical Trials”. This upcoming article, developed through a series of expert interviews, explores how unstructured health data—such as clinical notes, pathology reports, radiology narratives, genomic summaries, and imaging—can be made usable in eSource-enabled clinical trials. While structured EHR-to-EDC transfers have matured, unstructured data remains largely untapped and represents an estimated 80% of all health data.

The article features contributions from Task Force members and collaborators across the ecosystem: **Hospital perspective:** Memorial Sloan Kettering Cancer Center (MSK), Cambridge University Hospitals (CUH), University Hospital of Essen, **Sponsor perspective:** AstraZeneca, Johnson & Johnson, **Vendor perspective:** IgniteData, IOMED, ZS Associates. **Coordinating Body:** i~HD.

The study explores the potential of AI and natural language processing (NLP) to structure unstructured data and outlines the challenges of regulatory-grade validation. The authors advocate for hybrid interoperability models using *OMOP CDM* and *HL7® FHIR®*, demonstrating how transactional and analytical standards can work together to support compliant, scalable automation. The study offers both technical insights and strategic perspectives, framing unstructured data as a necessary frontier in the broader vision for digital-first clinical research.

These publications have and will strengthened the Task Force’s visibility, academic grounding, and influence across operational and policy communities.

4.2 White Papers: Overview

The Task Force developed and released three core white papers, as the first deliverables during 2024–2025, each designed to address a specific phase of eSource implementation and scale-up:

- **D1. Early Adopters’ Minimum Criteria for Success.** This white paper defines baseline requirements for both clinical trial sites and sponsors—such as EDC system readiness—as essential criteria for successful eSource implementation. Developed with input from early adopters, it identifies critical success factors across four domains: governance, technical infrastructure, workflow integration, and regulatory alignment. These criteria have been applied by Task Force hospitals to assess internal readiness, guide onboarding conversations with sponsors, and inform vendor selection. The framework offers a scalable starting point for institutions at varying levels of digital maturity and has been adopted within the Site Reference Group as a self-assessment tool to support structured implementation planning.
- **D2. Selected KPIs for eSource-Enabled Trials.** This white paper defines eight harmonized performance indicators to evaluate efficiency, user experience, interoperability in trials and scalability across trials using EHR-to-EDC integration. Together, these KPIs provide a foundation for cross-study comparison and scale-up validation. They have been co-developed by sponsor and site members; this framework defines eight harmonized performance indicators to evaluate and compare trial efficiency. These KPIs are:

(1) Accuracy of data transfer from EHR to EDC, (2) Completeness of structured data mapping, (3) Reduction in Source Data Verification (SDV), (4) Number of queries per CRF field, (5) Lock cycle time, (6) Interoperability readiness (HL7® FHIR® and system integration), (7) User-friendly CRC experience and perceived reduced site burden (via standardized satisfaction survey), (8) Overall efficiency and time savings in trial data handling.

A 2025 companion methodology further operationalizes **KPI #5 – CRC Satisfaction**, providing a standardized survey. The tool captures site usability and burden across vendors and trials and will support benchmarking in 2026.

These KPIs have been piloted by sites such as MSK, Mayo Clinic, and CUH, and are currently under review for broader rollout across the Task Force reference network.

- **D3. The eSource Playbook**
A comprehensive operational guide developed through workshops with hospitals and sponsors, the Playbook is structured around five implementation phases: **Preparation, Planning, Setup, Execution, and Post-Implementation Review.**

It includes:

- Interoperability design models (HL7® FHIR®)
- CDE mapping strategies
- CQI workflows and SOP integration
- Suggested governance templates and vendor checklists

The Playbook has been adopted as an internal planning tool by early adopters and is being expanded in 2025 with annexes on contracting, ethics, and business case development.

In June 2025, the Task Force published the first Annex to the eSource Playbook: *“eSource Data Flow Patterns: EHR-to-EDC Integration Models for Clinical Trials”*. This annex introduces a practical taxonomy of integration models—such as Direct Institution Bridge, Umbrella Institution Bridge, Health Information Exchange (HIE) Source Bridge, and Patient Health Record Integration (future-facing). It also classifies collaboration models like Sponsor-Centric Hub-and-Spoke and Multi-Vendor, Multi-Country Orchestration. This annex provides a shared vocabulary for assessing eSource strategies across sponsors, hospitals, and vendors. It supports real-world implementation planning and informs ongoing discussions with technical stakeholders and regulators.

All three white papers have been co-authored by members of the Core Team and validated through real-world input from Site and Sponsor Reference Groups, with aligned contributions from MSK, CUH, Mayo Clinic, Essen, and others.

4.3 Conference Presence: Summary of 12+ presentations across Europe.

In 2024–2025, the Task Force and its members delivered over a dozen high-profile presentations at leading clinical research conferences across Europe and the U.S. These sessions highlighted case studies, technical innovations, and collaborative frameworks central to eSource scale-up.

Key 2024–2025 presentations included:

- **SCOPE Europe** (Barcelona, Oct 2024) – i~HD led Panel with taskforce core members on *“Scaling eSource from Early Pilots to National Networks”*
- **Day of Biologics** (Basel, Oct 2024) – Keynote by i~HD on cross-stakeholder interoperability
- **Clinical Trials Conclave** (Nice, Feb 2025) – Keynote by i~HD on digital infrastructure and eSource maturity
- **NUM Annual Symposium** (Berlin, Feb 2025) – Keynote by i~HD on hospital digitization readiness (German network focus)
- **ACDM Europe** (Prague, Mar 2025) – Panel chaired by i~HD on implementation tools and Playbook guidance
- **SCDM Europe** (Brussels, Apr 2025) – Workshop on KPIs and data monitoring approaches
- **15th Annual Outsourcing in Clinical Trials Europe** (Barcelona, Apr 2025) – Keynote on sponsor-site collaboration
- **Newmarket Strategy Event** (Royal Society of Medicine, London, May 2025) – Panel session on governance and reference groups in UK on the future of healthcare and life sciences research.

- **Veeva Clinical Data Innovation Forum** – May 2025 (New York). MSK presentation on scaling of eSource/EHR-to-EDC technology from the perspective of a large academic medical center in the US, and a large pharmaceutical company.

Upcoming Q3–Q4 2025 appearances:

- In September, **Clinical Data Talks** (hosted by CRScube) will feature a video podcast with Dr. Mats Sundgren of i~HD titled **“Leveraging eSource in Clinical Data Collection.”** The episode explores the goals of the eSource Scale-Up Task Force—including interoperability, CRC burden reduction, and KPI-based evidence generation. Part of a global digital innovation series, it offers an accessible introduction to eSource for clinical data professionals.
- **DPHARM** Conference (Philadelphia, Sep 2025) MSK Session on Disruptive Innovations to Modernize Clinical Research
- **SCDM Global** (Baltimore, Sep 2025) – Discussion on international KPI benchmarking
- **SCOPE Europe** (Barcelona, Oct 2025) – Joint hospital-sponsor panel
- **Marcus Evans Evolution Summit** (Montreux, Oct 2025) – Keynote on new era of Clinical Trials with eSource, AI
- **i~HD Annual Conference & First eSource Showcase** (Ghent, Dec 2025) – Plenary session and track presentations

These conferences have provided a critical platform for disseminating tools, aligning stakeholder expectations, and expanding the reference network. Several hospitals and sponsors joined the Task Force after attending these sessions or engaging in follow-up consultations.



5 Reference Networks: Expanding the Ecosystem

The Site and Sponsor Reference Groups launched in 2025 are critical enablers of the Task Force’s scale-up strategy. These networks provide a practical foundation for implementation, benchmarking, and peer learning across diverse geographies and institutional types.

The **Site Reference Group** currently includes over a dozen academic and research hospitals across Europe and the U.S. These members contribute to the validation of deliverables, testing of KPIs, and peer-to-peer learning. The ambition for 2026 is to expand this network to at least 40 sites, including new representation from the U.S. and the Asia-Pacific region.

The **Sponsor Reference Group** is being established to provide critical input on interoperability, feasibility, contracting models, and broader stakeholder engagement. While no memberships are yet confirmed, discussions are ongoing with more than five pharmaceutical companies, with the aim of forming a group of up to 10 sponsors in 2026.

In addition, a new **Technical Vendor Reference Group** will be established in 2026. This group will include key EHR-to-EDC integration providers, EHR platform vendors, and middleware partners to ensure alignment on implementation standards, data exchange formats (HL7® FHIR®), and compliance frameworks.

Together, these reference networks form the collaborative infrastructure to guide real-world adoption, harmonize best practices, and prepare the ecosystem for scalable, standards-based eSource implementation.

5.1 Positioning in the Global eSource Landscape

The i~HD eSource Scale-Up Task Force stands out by connecting the dots between global standards, European interoperability efforts, global eSource related initiatives and real-world implementation. While initiatives like [TransCelerate's eSource programme](#) and the [HL7 Vulcan Accelerator](#) focus on standards and interoperability, several task force sponsors actively participate through TransCelerate's EHR connectivity initiative. Similarly, the Task Force is connected with the [Society for Clinical Data Management \(SCDM\)](#) eSource team, avoiding duplication of effort. The Task Force work complements and operationalizes these global efforts.

On the European stage, members of the task force engage with key programs such as [xShare](#)—the EU-funded Yellow Button initiative to empower patient data portability—and [Hospitals on FHIR](#), a community-of-practice boosting hospital interoperability maturity. By joining these, we ensure our operational tools align with emerging health data ecosystems under the European Health Data Space (EHDS).

Operating in a pre-competitive, consensus-driven model, the Task Force brings hospital, sponsor, and technical voices together to generate actionable outputs rather than theoretical frameworks. Our deliverables—readiness criteria, KPI instruments, CRC survey methodologies, and vendor-aligned Playbook annexes—drive harmonized eSource execution across sites and sponsors.

This avoids duplicating work from organizations like CDISC, which focus on data modelling in view of regulatory submission, or HL7 Vulcan, which develops FHIR Implementation Guides in view of clinical research and hosts webinars supporting the enablement of clinical research infrastructure. Instead, we translate their foundational outputs into pilot-ready, repeatable processes, accelerating value delivery through shared infrastructure and coordinated roll-out.

The Task Force approach exemplifies a clear division of labour: standards + interoperability by global initiatives, and on-the-ground implementation by Task Force partners. This synergy enables hospitals and sponsors to harmonize eCRF design, technical onboarding, and KPI benchmarking—delivering operational outcomes faster and more sustainably than any organization could achieve alone.

6 Evidence & Validation

6.1 Performance Monitoring via KPIs

The Task Force's KPI framework (outlined in White Paper D2) has been piloted at multiple reference sites and offers a harmonized method for tracking the benefits and operational impact of eSource adoption. Key indicators include:

(1) Accuracy of data transfer from EHR to EDC, (2) Completeness of structured data mapping, (3) Reduction in SDV, (4) Number of queries per CRF field, (5) Lock cycle time, (6) Interoperability readiness, (7) User-friendly CRC experience and perceived reduced site burden, (8) Overall efficiency and time savings in trial data handling.

In 2025, a major advancement was the development of a [Standardized CRC Satisfaction Survey](#), based on KPI #5. This methodology—co-authored by Task Force members from hospitals, sponsors, and technology partners—provides a validated, user-centred measure of system usability, site burden, and adoption.

The survey includes nine Likert-scale questions and two open-ended prompts. Key constructs include ease of learning, confidence in data accuracy, time efficiency, and overall job satisfaction. The scoring method focuses on “positive satisfaction” (Likert scores ≥ 5) and enables both cross-site comparison and longitudinal tracking. Optional metrics such as response time, audit trail trust, and user support help round out the analysis. This KPI will be systematically deployed across selected trials in 2026.

6.2 Case Study Summaries: Evidence from MSK, Cambridge, Mayo, MD Anderson, City of Hope.

- **MSK:** Time savings of +5 minutes per data point, with reduced query burden and strong CRC endorsement.
- **Cambridge:** Increased confidence in lab data accuracy; successful pilot of CRC satisfaction survey tool.
- **Mayo Clinic:** Validated SDV reduction, integrated KPI tracking into EDC workflows
- **MD Anderson & City of Hope:** Ongoing analysis of query trends and CRC user experience
- **University Hospital of Essen:** Showed improved transfer traceability; participated in unstructured data study

These case study results are consolidated and analysed in the *Applied Clinical Trials (April 2025)* article, “Scaling eSource Across Oncology Centers.” Co-authored by six institutions across the U.S. and Europe, the publication provides validated, peer-reviewed evidence supporting the operational gains outlined above. It also establishes a four-phase roadmap for implementation and forms the basis for upcoming annexes on value demonstration and institutional readiness.

These outcomes reflect early evidence of improvements in data quality, efficiency, and user satisfaction—key priorities tracked by the Task Force's KPI framework. Together, these findings form the foundation for broader KPI deployment and the development of a shared **eSource Evidence Repository** in 2026.

7 Strategic Priorities for 2025-2026

In 2026, the Task Force will transition from foundational development to operational scale-up, with an emphasis on evidence generation, vendor collaboration, and broader institutional onboarding. Core priorities include

- 1. Playbook Development and Scaling Support.** The eSource Playbook will continue to serve as a central implementation resource and will be updated quarterly. In addition to ongoing refinements, several new annexes are planned to support institutions and sponsors in addressing specific scale-up challenges. Upcoming annexes will include:
 - *Annex 2: Value Demonstration* – Quantifying benefits such as reduced Source Data Verification (SDV), CRC time savings, improved data quality, and shortened lock cycle times.
 - *Annex 3: Contracting Models* – Offering templates and guidance on master service agreements (MSAs), data reuse terms, governance frameworks, and cross-institutional legal alignment.
 - *Annex 4: Therapeutic Area Innovations* – Exploring the use of eSource in high-data-density domains such as oncology, genomics, and imaging, including AI-driven workflows and unstructured data integration.
 - *Annex 5: CRF Design* – Listing best practices in CRF designs for studies where both eSource sites as well as manual entry sites participate.
 - *Annex 6: Data Scope Extension Approach* – Describing methodology, thought process and considerations for sites and sponsors to assess feasibility of expansion of data scope for EHR2EDC.

Educational content based on the Playbook will include three new onboarding modules for sponsors and hospitals. A masterclass offering is under consideration and may be pursued through separate funding or participation fees.

- 2. Site Maturity and Reference Network Expansion.** The Task Force aims to grow the Site Reference Network to a total of 40 hospitals, including 10 “premium” sites with advanced digital readiness. Maturity criteria will be further developed, and a structured onboarding framework—supported by a digital readiness catalogue—will guide new site engagement and readiness assessment.
- 3. Awareness, Evidence, and Communication.** Efforts will focus on high-impact dissemination, including peer-reviewed publications, webinars, and conference presentations. A particular emphasis will be placed on presenting at events with strong institutional and hospital attendance. Publications will prioritize evidence generation across sponsors, sites, and studies—anchored in the Task Force’s KPI framework and maturity assessment tools. As part of this effort, the *CRC Satisfaction Survey (KPI #7)* will be deployed across multiple hospitals to benchmark user experience and validate operational benefits in live eSource trials.
- 4. Implementation Guidance and Project Support.** While direct implementation funding will not be provided, the Task Force will offer structured guidance to institutions at various stages of eSource readiness. A key deliverable will be the launch of the *eSource Site Maturity Assessment Tool*, enabling self-evaluation and tailored onboarding support for hospitals. This

tool will help align internal capabilities with sponsor requirements and readiness criteria defined in the Playbook.

5. **Sponsor Engagement and Expansion.** The Sponsor Reference Group will continue to evolve through active dialogue with pharmaceutical companies. The goal is to reach 10 committed sponsor members in 2026, fostering cross-sponsor alignment on contracting, feasibility, and regulatory strategies. Sponsors will also play a key role in validating Playbook updates, contributing to annex development, and co-authoring case studies and best practice guides.
6. **Technical Vendor Collaboration.** The Task Force will launch a *Technical Vendor Reference Group*, engaging middleware providers, EHR platform vendors, and integration tool developers. This group will align on standards (e.g., HL7® FHIR®), define scalable interface models, and support implementation blueprints. Its goal is to ensure consistent, vendor-neutral integration patterns that enable repeatable, compliant, and scalable eSource adoption across diverse healthcare settings.

8 Annex: Glossary of Terms

Term	Definition
Champion Hospitals	Leading healthcare institutions that are early adopters and innovators in eSource technologies.
Continuous Feedback Loop	A process where data from ongoing trials is continuously reviewed and used to make real-time adjustments.
Data Interoperability	The ability of different systems, such as EHR and EDC systems, to communicate and exchange data seamlessly.
Data Mapping	The process of defining the data elements in the EHR that will be transferred to the Electronic Case Report Form (eCRF) within the EDC system.
Data Validation	The process of ensuring that data transferred from EHR to EDC is accurate, complete, and reliable.
eSource or EHR2EDC	A streamlined process designed to transfer routinely collected EHR data relevant to clinical research and RCT into an EDC system.
Electronic Data Capture (EDC)	A clinical trial software system used to collect, manage, and store data.
Electronic Health Record (EHR)	A digital version of a patient's medical history that can be a source of data for clinical trials.
Fast Healthcare Interoperability Resources (FHIR®)	An interoperability standard for healthcare data exchange, developed by HL7®.
GDPR (General Data Protection Regulation)	A European Union regulation that protects the privacy and security of individuals' data.
HIPAA (Health Insurance Portability and Accountability Act)	A U.S. law designed to protect the confidentiality and security of patient health information.
Pilot Study	A small-scale study conducted before the full-scale clinical trial to test the feasibility of the eSource system.
Post-Implementation Review	A process conducted after eSource system implementation to evaluate its success and document lessons learned.
Randomized Clinical Trial (RCT)	A type of clinical trial where participants are randomly assigned to different treatment groups to evaluate the efficacy and safety of interventions for regulatory submission.
Real-Time Data Monitoring	The ability to continuously track and monitor clinical trial data as it is collected.
Regulatory Compliance	Adherence to rules, regulations, and guidelines that govern clinical trials and patient data handling.
Risk Mitigation Strategy	A plan developed to identify and address potential risks in eSource trials.
ROI (Return of Investment)	A measure of the financial benefits achieved through eSource implementation relative to the cost incurred, often expressed as a percentage.
ROH (Return of Health)	A measure of the health benefits achieved through eSource implementation, including improved patient outcomes, faster trial timelines, and enhanced trial efficiency
Scalability	The ability to expand eSource technology implementation across multiple sites and trials without losing performance.
Source Data Verification (SDV)	A process to confirm that the data collected in a clinical trial's EDC system matches the original source data.
Stakeholders	Individuals or groups involved in the clinical trial process, such as sponsors, research organizations, and healthcare providers.
Vulcan CAB catalogues	Vulcan CAB (Change Advisory Board) catalogues are structured frameworks within the HL7 Vulcan initiative that standardize data categories, support interoperability best practices, and facilitate the integration of clinical and research data across diverse healthcare systems.

Acronym	Meaning
EHR	Electronic Health Records
EDC	Electronic Data Capture
CRC	Clinical Research Coordinators
CQI	Continuous Quality Improvement
i~HD	The European Institute for Innovation through Health Data
SDV	Source Data Verification
FHIR®	Fast Healthcare Interoperability Resources
AI	Artificial Intelligence
ML	Machine Learning
GCP	Good Clinical Practice
MSA	Master Services Agreements
CDA	Confidential Disclosure Agreements
SDLC	System Development Life Cycle
IRB	Institutional Review Board
DMP	Data Management Plan
CDA	Confidential Disclosure Agreement
E2E	End to End
eCRF	Electronic Case Report Form
UAT	User Acceptance Testing
SOP	Standard Operating Procedure
ROI	Return On Investment
ML	Machine Learning
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
RCT	Randomized Clinical Trial
ROH	Return On Health
EMA	European Medicines Agency
HIMSS	Healthcare Information and Management Systems Society
UAT	User Acceptance Testing
ICT	Information and Communication Technology