eSource
Scale Up Task Force

Technology Vendor Reference Group

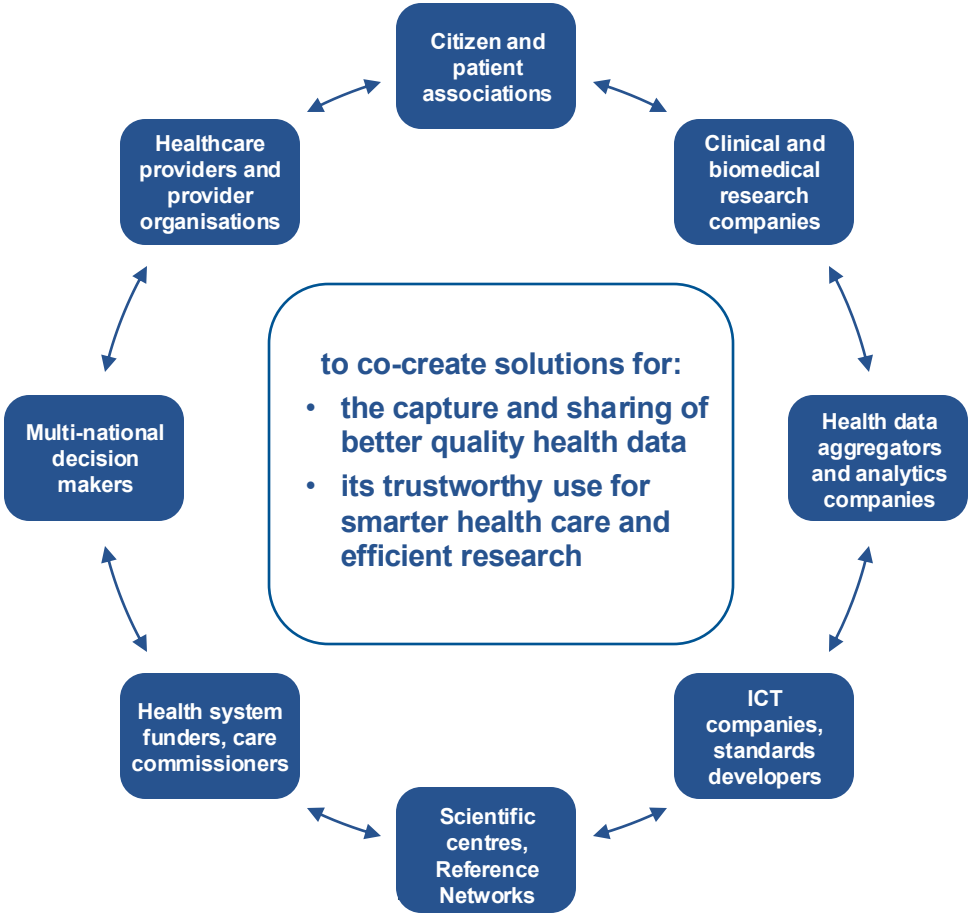
Webinar – 25 September 2025

Agenda

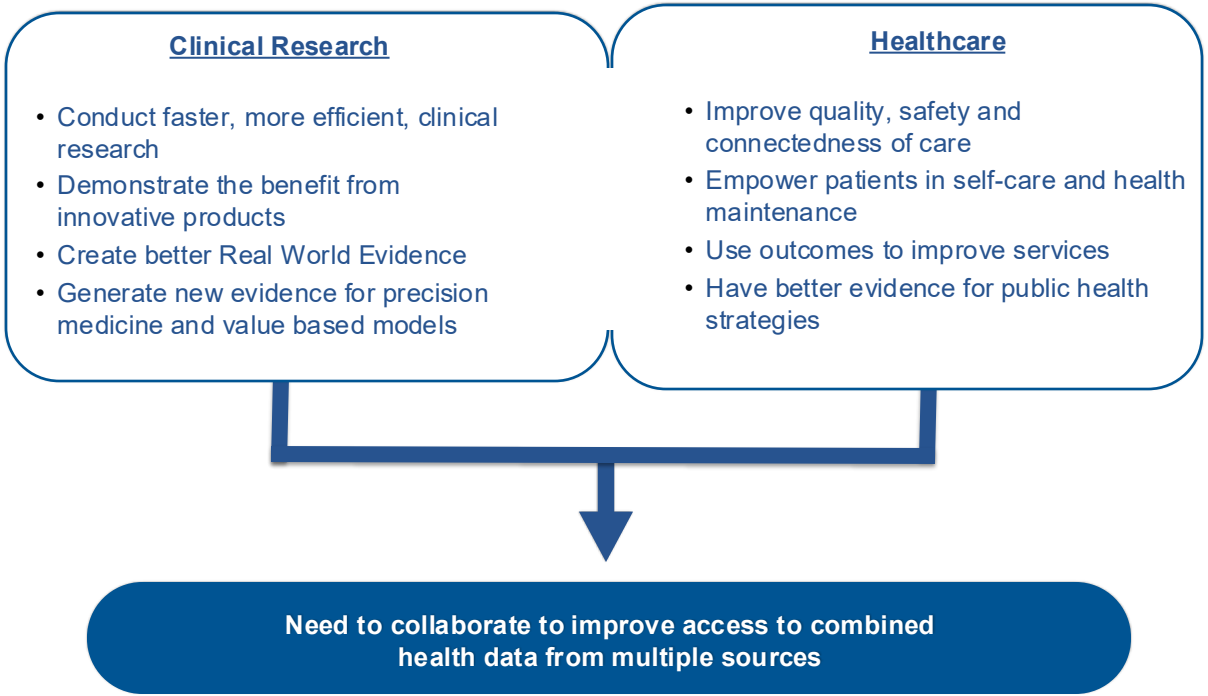
1. Introduction to i~HD
2. eSource Scale-Up Taskforce
3. Site and Sponsor Members Perspectives
4. Technology Vendor Reference Group Membership
5. Outlook
6. Q&A
7. Closing

Introduction to i~HD

i~HD is a neutral not for profit body, bringing stakeholders together



i~HD targets a convergence of ambitions from health data



i~HD tackles the challenges with using health data

Clinical Research data needs

Healthcare data needs

Catalysing the reuse of health data

i~HD eSource Task Force: accelerating eSource adoption

eSource

Scale Up Task Force

eSource Scale Up Task Force

eSource Scale Up Task Force

Coordinated by i~HD for member organizations to drive data interoperability and champion EHR as eSource

Purpose

- Drive and scale the adoption of Electronic Health Record (EHR) as eSource technology across pharma/biotech companies and hospitals
- Promote alignment across members and to networks to adopt harmonized and efficient practices and processes
- Engage with relevant organisations and stakeholders involved in eSource EHR initiatives

eSource
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Outputs

- Published reports, publications, webinars, position papers, recommendation, presentations, meetings

Core Members

Cambridge University Hospitals NHS Foundation Trust
Memorial Sloan Kettering Cancer Center
University Medicine Essen
sanofi
Johnson&Johnson
REGENERON
Lilly A MEDICINE COMPANY
AstraZeneca
i~HD The European Institute for Innovation through Health Data

Reference Groups

Study Sites
Sponsors

Technology Vendor Reference Group

i-HD EHR as eSource Task Force: 2025 Scope

Key areas for collaboration

Site Readiness

- Direct Data transfer readiness requirements for hospitals
- Readiness checklist
- Awareness/education webinars to sites

Industry Playbook

- Establish a playbook for deploying EHR direct data transfer to Sponsor
- Define common data elements catalog
- Define minimum requirements for EHR to Sponsor solutions

Regulatory

- Clarifying regulatory guidance interpretations,
- Exploring acceptable approaches and validation rules to collect regulatory-grade unstructured data using eSource technology

Early Adopters' Minimum Success Criteria for eSource Implementation

Unified Success through Collaboration

Health Care Organizations (HCOs)

- Clinical Trial Capacity
- EHR Compliance (ISO, ALCOA, EMA)
- FHIR® Adoption with Leadership Support
- Standardized Clinical Trial Coding (LOINC, SNOMED, ICD-10 / 11)
- Dedicated eSource Team
- Security & Privacy Compliance

Middleware EHR2EDC Vendors

- FHIR® -based & EHR-Agnostic approach
- HCO/user acceptance
- ODM Standards for Study Setup purposes
- Vulcan Implementation Guide Adherence
- Transparent Data Flow & Mapping
- Compliance with GDPR, HIPAA, CFR 21
- Data Use Limited to Transfer to Sponsor
- Traceability & Audit Trails

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EHR Vendors

- EHR Compliance (ISO, ALCOA, EMA, EHDS)
- FHIR® Access with Future Expansion Plans
- Research-specific Functionality
- Collection of Wearables & External Data

EDC Vendors

- Unified eCRF for Manual & EHR-to-EDC Entry
- Lab Ranges Integration through FHIR® Standard
- Seamless Automated Data Integration
- Real-time Data Management & Audit Trails

Task Force White Papers*

Selected KPIs for eSource enabled trials

- **Measuring eSource Impact** – Defines KPIs for efficiency, data quality, and site workload in EHR-to-EDC integration.
- **Optimizing Trial Performance** – Tracks data accuracy, workflow automation, and reduced manual entry to streamline operations.
- **Driving Adoption** – Establishes a standardized framework to support industry-wide eSource adoption.

eSource Playbook

- **Structured Implementation – Guides** with five key phases: Preparation, Planning, Setup, Execution, and Review.
- **Standardizes workflows**, reduces manual data entry, and enhances real-time data accuracy, accelerating trial timelines and minimizing errors.
- **Future Collaboration -** Promotes FHIR interoperability, scalability, and digital transformation in clinical research.

* Available on i-HD website

White papers

White Paper	Purpose	Key Features
Minimum Success Criteria *(Jul 2024)*	Define baseline conditions for initiating eSource trials	Readiness checklist across organizational, technical, compliance, and staffing domains
Selected KPIs *(Dec 2024)*	Measure success of eSource implementations	8 standardized indicators including data accuracy, SDV reduction, CRC burden, and mapping reusability
KPI Annex: CRC Satisfaction survey for eSource-Enabled Trials *(May 2025)*	Measure satisfaction of CRC	11 standard questions to measure satisfaction
eSource Playbook *(Mar 2025)*	Provide a phased, step-by-step implementation guide for sponsors and sites	5-phase model (Preparation, Planning, Setup, Execution, Review); tailored workflows and CDE guidance
Playbook annex 1: eSource Data Flow Patterns: EHR-to-EDC Integration Models for Clinical Trials *(Jun 2025)*	Describes different eSource patterns and their pros/cons	Describes four core eSource integration patterns for leveraging Electronic Health Record (EHR) systems in clinical trials as well as 3 collaboration models

Site and Sponsor Members Perspectives

Memorial Sloan Kettering's Why

The Problem

Manual burden: 400 CRCs manually manage data for 1,800+ research studies at MSK.

Risk: Manual entry slows trials, introduces data quality issues and increases overall costs.

Systemic issue: This is an industry-wide challenge, extending beyond MSK.

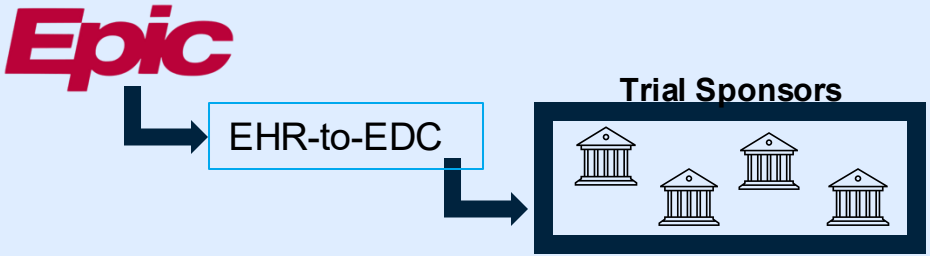
The Solution

Search for solutions (2022–2023): MSK's Clinical Research Innovation team evaluated ways to reduce data entry costs.

Selected partner: enables automated EHR-to-EDC transfers. Prioritized EHR and EDC agnostic solutions.

Standards-based: Uses FHIR to map and send data accurately.

Scaling up: From small pilot at MSK to scaling across portfolio and adoption at major cancer centers and global sponsors.

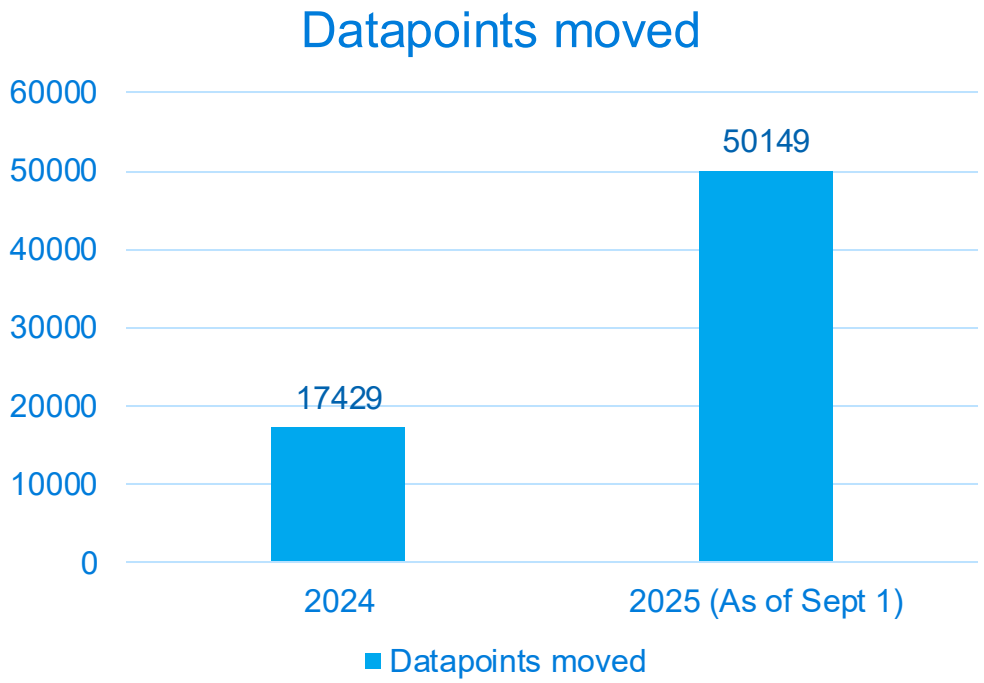


Scalability at Memorial Sloan Kettering

MSK Scaling Across Research Portfolio

- *Industry sponsors with EHR-to-EDC agreements*
- *New IIT studies at MSK*
- *Multicenter studies with EHR-to-EDC sites*

Memorial Sloan Kettering Cancer Center



Lilly's Why – The Business Value

Reduce Site Burden

- Improve satisfaction for over-worked and under-staffed sites
- Minimize the reliance on manual entry
- Enable investigator staff to focus on more critical tasks

KPI: Change in lag time between participant visit & EDC populated data

Improve Data Quality

- Reduce the need for Source Data Verification (SDV)
- Ensure higher data integrity and reliability throughout the trial
    - *20% of the total cost of a trial is spent on data duplication and verification

KPI: Change in number of queries attributed to transcription errors

Internal Efficiencies

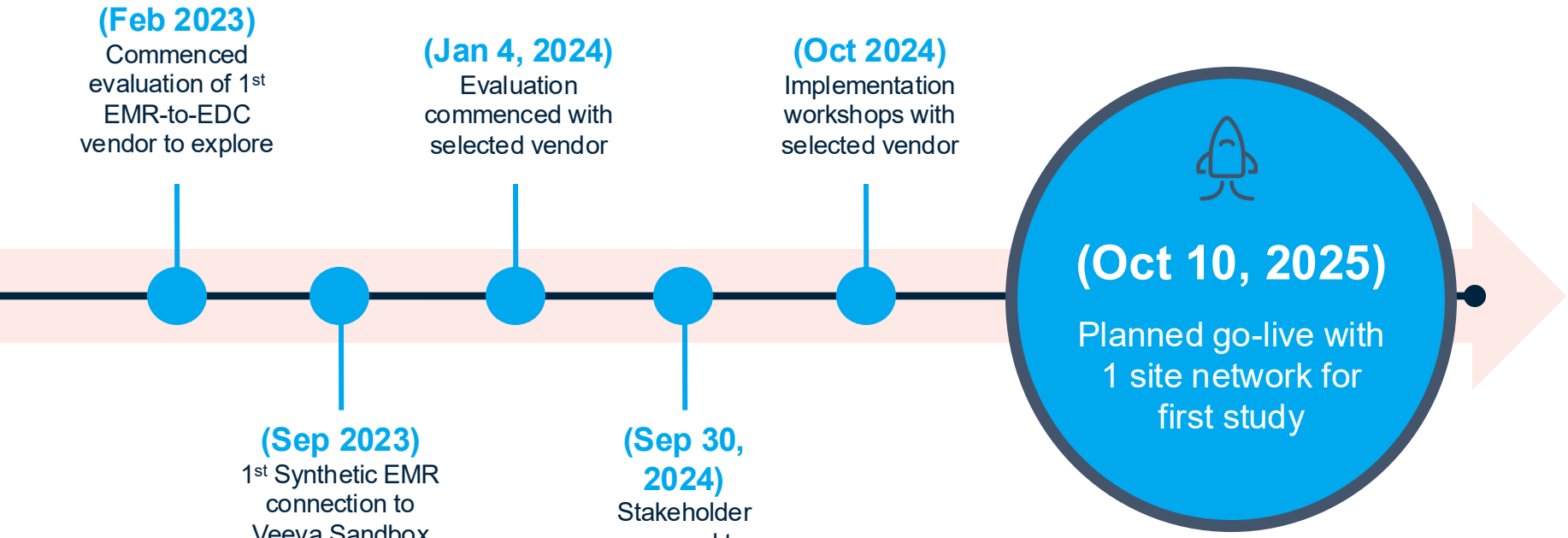
- Decrease time and costs spent on query resolution and SDV
- Faster access to accurate real-time data
- Align with regulatory guidance:

  "FDA encourages sponsors and clinical investigators to…. **use EHR and EDC systems that are fully interoperable or fully integrated**."

KPI: Change in overall number of queries

*Source: *Journal of the Society of Clinical Data Management, 2021*

Lilly's Timeline



Technology Vendor Reference Group

Technology Vendor Reference Group

Benefits

- Part of the eSource Taskforce Landscape (sponsors – sites – tech vendors – connected with other eSource initiatives such as those within TransCelerate, Vulcan, …)
- Fast access to user requirements, deliverables and opportunity for feedback
- Preferential invitee and active participation (webinars / conference / round tables / workshops / …) organized by the eSource Taskforce
- Access to insights from eSource leaders
- 3/year a webinar – all eSource partners – achieved outcomes – next steps
- Logo on i~HD website
- Preferential sponsor activities organised by the eSource Taskforce

Requirements

Yearly Tech Vendor Reference Group fee (yearly fee approved in iHD management Board)

< 250 employees = 5000 Euro/year

> 250 employees = 7500 Euro/year

Link: [eSource Technology Vendors Reference Group]

In-kind Contributions

Discuss, review, and mirror deliverables from working streams (on demand)

What’s next

Link: Annual Conference

- Achieving informed, equitable and safe EHDS opt outs
- Lessons learnt from data space forerunners
- AI systems need safe drivers: making users competent and confident
- Creating, sharing and using excellent European EHR exchange format data
- The vision of health data in research
- Privacy preservation within real and synthetic data spaces
- Ensuring the quality and safety of digital health innovations
- Innovative uses of the health summary in your pocket
- Adoption of AI in healthcare
- How will EHDS Health Data Access work?
- Real-World Data for clinical research: it's time to scale up!
- Improving the quality of EHR data, for continuity and patient safety
- How to get patients ready to use AI?
- How to prepare to be an EHDS data holder
- Generating and trusting Real-World Evidence
- Where next for the European EHR Exchange format?

[Link: eSource Conference]

Program eSource Conference 2025 2nd December

Dec 2nd 2025	Opening		Dipak Kalra	Opening
	Setting the eSource scene (Chair: Christophe Maes)	Keynote	Mats Sundgren	The Future of Trial Efficiency: EHR as eSource at Scale Transforming Clinical Trials
		Keynote	Dipak Kalra	EHR as eSource and the EHDS Unlocking Health Data for Clinical Research
		Keynote	EMA	Regulatory requirements and perspectives
		Keynote	TBC	Why eSource Matters for Clinical Sites: Benefits, Value and Operational Impact
		Keynote	Michael J. Ward	Why eSource Matters for Pharmaceutical Companies: Benefits, Value and Operational Impact
			Q&A	
	Getting prepared (Chair: Mats Sundgren)		Peter Casteleyn	The Journey to Scale-Up eSource
			Christophe Maes	Clinical site readiness: Requirements to Participate in eSource enabled Clinical Trials
			Scott Russel / Jens Declerck	Falling in love with the root cause in data quality
			Amy Cramer & Joseph Lengfellner	Scaling eSource for impact: proving feasibility, deliverling value: Vulcan suported business Use cases
			Q&A	
	Setup for the first study (Chair: Joseph Lengfellner)		Felix Nensa	Why and how to get FHIR ready at a Clinical Site
			Lars Fransson	eSource Data Flow Patterns disclosed
			data workstream	Scoping the Data for eSource
			Becky Kush	Ensuring eSource Quality Through Standards
			Q&A	
	Scaling (Chair: Peter Casteleyn)		Mats	The Scalability Roadmap: Dimensions, Factors, and Implementation Pathways
		Panel	TBC TBC TBC	Panel discussion on Scaling-Up eSource
				Linking with other eSource Initiatives
	Closing remarks conference day		Dipak Kalra	
	Networking drink			

Closing

Summary & Conclusions

If innovations such as eSource/EHR-to-EDC operate at full swing, this will allow us to perform research that otherwise wouldn't happen and to develop medicines that otherwise would never make it to the patient

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Thank You

Scaling up the technology opens new avenues for collaboration!

This is exemplified by deploying the output from new innovative solutions which involves pharmaceutical companies, hospitals, along with technology vendors and academic partners.

It serves as a prime example of the African Proverb:
“If you want to go fast, go alone; if you want to go far, go together”