SCDM Live

Advancing Oncology Trials: Integrating EHR and EDC Systems through eSource Technologies

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Advancing Oncology Trials: Integrating EHR and EDC Systems through eSource Technologies

Friday April 11th, 2025

RICHARD YEATMAN
COO, IgniteData

MATS SUNDGREN
Sr. Director, i-HD

STEPHAN CICHOS
Strategic Project Leader - Clinical Data Strategy & Operations, Bayer AG

Outline

- Background and outlook on eSource Technology
  - Mats Sundgren, i-HD
- From a Vendor Perspective – Results from studies at MSK
  - Richard Yeatman, IgniteData
- From a Sponsor Perspective – Bridging the Gap
  - Stephan Cichos, Bayer AG
- Q&A Panel
- Closing

The Urgency for Change in Clinical Trials

- **Oncology trials** generate over 10,000 data points per patient, driven by genomic advances, digital tools, and personalized medicine.
- **Over 50% of trial data is duplicated** between research systems and EHRs, with 20% of study costs spent on verification.
- **Managing real-world data and digital endpoints** is becoming costlier and slowing trial execution.
- **eSource technology, powered by advanced EHRs and FHIR interoperability**, can eliminate redundancies, cut costs, and accelerate trials.

The question is no longer if eSource will transform ***clinical trials—but how fast we can implement it.***

What is EHR-to-EDC or eSource?

Transfer Process: EHR to EDC (Electronic Health Record to Electronic Data Capture), also known as **eSource**, involves moving EHR data to an EDC system or sponsor's database for Randomized Clinical Trials (RCTs).

Compliance and Consent: The transfer process includes quality assurance and adherence to regulatory eSource guidelines, with the patient's consent, and without replacing manual data entry or causing data redundancy.

Data Types: The EHR data utilized typically comprises **structured data** or coding standards (e.g., ICD, SNOMED CT, LOINC, HL7) such as laboratory results, vital signs, medications, diagnoses, and patient demographics.

Why eSource?

eSource: Can Transform the Way We Do Clinical Trials in Collaboration with Hospitals & Industry

EHR-to-EDC ≠ Mining Patient Hospital Records

Reduces site burden
- Less time spent looking up data already in EHR
- Reduces manual data entry
- Eliminates duplicate data entry
- Generates fewer queries

Increasing site efficiency through automation boosts
- Potential to increase patient density at sites = less sites

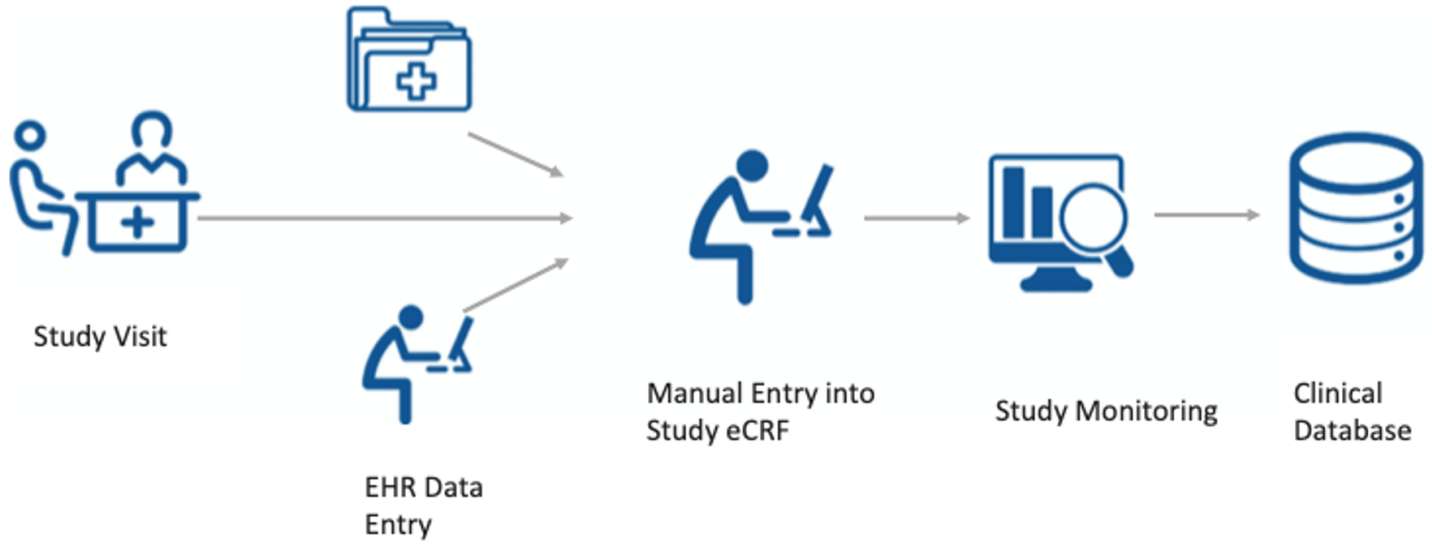
Reduces Sponsor and SDV burden

Improves data quality
- Less EHR to EDC transcription errors
- Greater traceability for end-to-end data flow

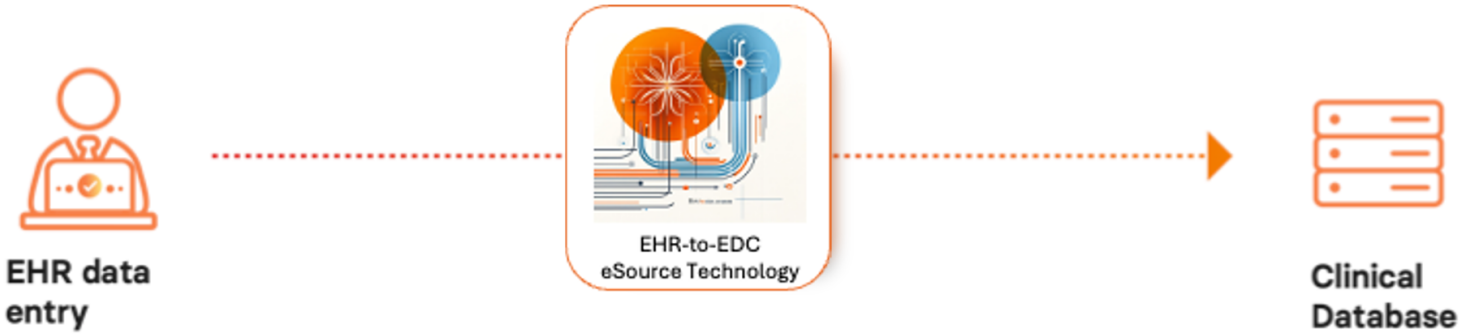
Sponsor of choice

Data Automation Technology vs Existing Methods

Existing methods

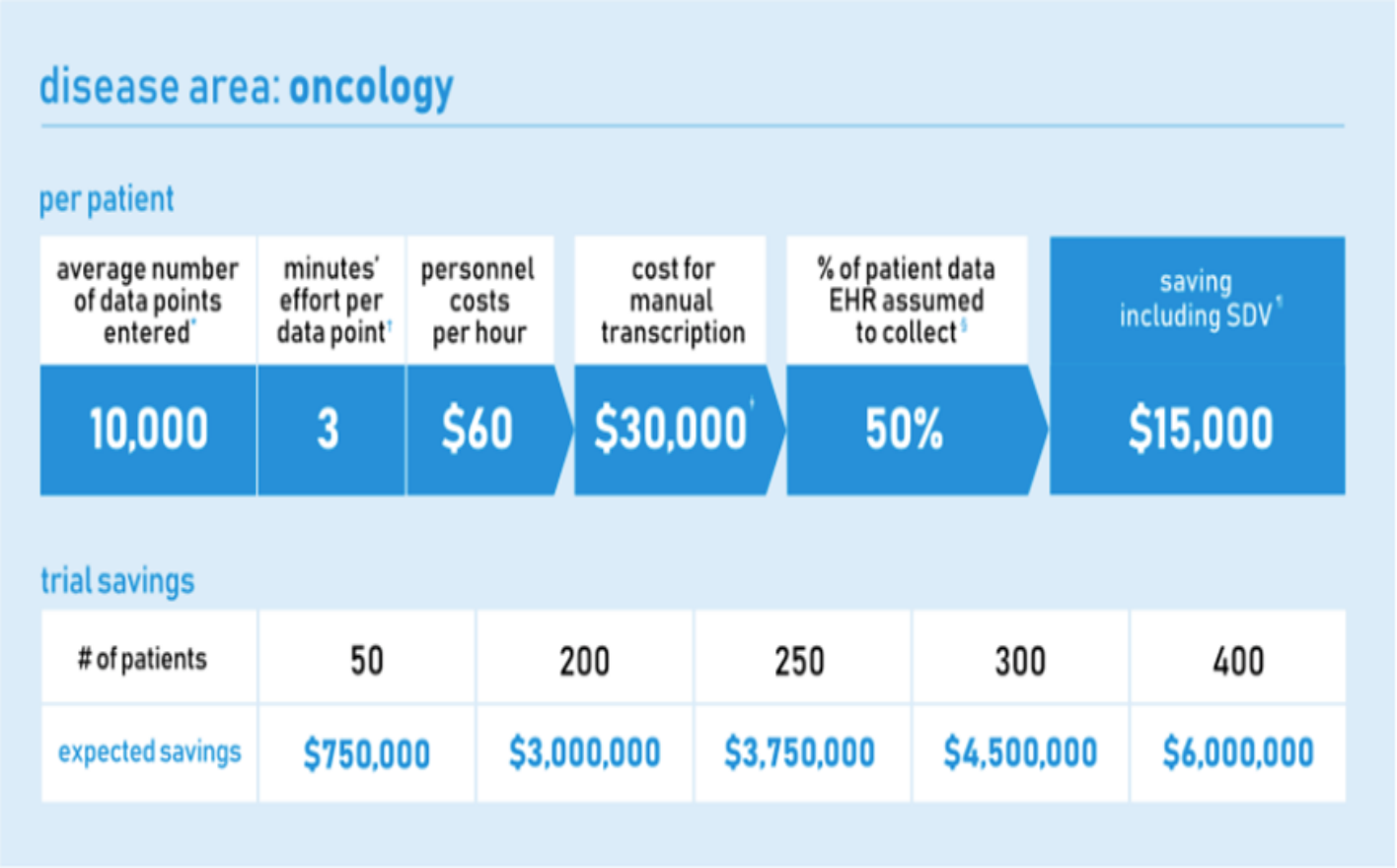


Data automation technology



Three Minutes and 5000 hours

Today it takes +3 minutes* per data point spent by local study personnel (e.g., searches, manual entry, check, review, resolve queries in EDC etc.) for 10 patients and 10.000 data points per patient on one study is equal of 5000 hours.



Replacement of manual re-keying and verification could result in cost savings of:

$15,000 per patient

87,500 hours

in a 3.5 million data point study

Illustration produced by Sanofi during the EHR2EDC consortium project.

*** Research from six oncology centers demonstrates that manual transcription requires an average of at least five minutes per data point.**

(Sundgren M, Andrews L, Burge S, Bush M, Fritsche A, Nensa F, Lengfellner J. Scaling eSource-Enabled Clinical Trials: Challenges, Opportunities, and Strategic Outlook for Oncology Research Centers. Applied Clinical Trials. 2025; 37(1).)

eSource Scale Up Task Force

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

Purpose

- Drive and scaling 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
Scale Up Task Force

Outputs

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

Core Members

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

Reference Groups

Study Sites
Industry

Technology Network

Early Adopters' Minimum Success Criteria for eSource Implementation

Unified Success through Collaboration

Health Care Organizations (HCOs)

- Clinical Trial Capacity
- EHR Compliance (ISO, ALCOA, EHDS)
- 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

eSource
Scale Up Task Force

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
Scale Up Task Force

* Available on i-HD website

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.

Insights from MSK

DATA MANAGEMENT

Streamlining Clinical Trials with eSource: Insights from MSK

Memorial Sloan Kettering use case explores the potential of EHR-to-EDC.

Mats Sundgren, PhD
Industry Science Director, i-HD

Gynet Santiago
Clinical Research Coordinator, Memorial Sloan Kettering Cancer Center (MSK)

Joseph Lengfellner
Sr. Director, Memorial Sloan Kettering Cancer Center (MSK)

Today, clinical trial data collection faces increased complexity due to data duplication between research systems and electronic health records (EHRs), particularly in oncology studies. Manual processes, such as data entry, consume significant time and resources. Over 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.[1]

The number of data points collected in oncology trials has surged dramatically over the past decade, driven by advances in genomic technologies, digital health tools, and personalized medicine. While this increase in data volume enhances our ability to understand and treat cancer more effectively, it also presents significant challenges in data management and analysis. In typical Phase III oncology trials, approximately 10,000 data points are collected per patient. However, in trials incorporating genomic and digital health data, this number can multiply ten to a hundredfold.[2,3]

As a result, study sites, particularly clinical research coordinators (CRCs), face increased workloads, complex data management tasks, and the need for specialized training, leading to higher personnel costs. Sponsor companies incur additional expenses due to investments in advanced data management tools, extended trial timelines, and source data verification (SDV). To mitigate these challenges, sites and sponsors must explore innovative solutions, collaborate with stakeholders and vendors, and ensure regulatory compliance to improve efficiency, reduce costs, and enhance cancer treatment outcomes.

EHR to electronic data capture (EHR-to-EDC), or eSource technology and processes, offers a promising solution, delivering significant time and cost savings by streamlining data transfer.[4,5] The European EIT Health-supported EHR2EDC project estimated a total time of three minutes per data point in oncology trials, demonstrating substantial efficiency gains.[4,5,6]

This paper presents a use case from Memorial Sloan Kettering Cancer Center (MSK), emphasizing the critical role of CRCs. It highlights the burden-some nature of current double-entry processes and supports the three-minute-per-data-point estimate. Additionally, it revisits the value generated for investigational sites and sponsors by introducing this technology, exploring the transformative potential of eSource for future clinical trials.

Methodology

The study employs a qualitative structured interview guide to understand the data entry process during clinical trials. An in-depth, semi-structured interview was conducted with an experienced CRC to gather insights into workflows, challenges, and perceptions regarding data entry tasks. Open-ended questions allowed for rich, nuanced responses, capturing the complexity and variability of the process. The validity and generalizability of the interview outcomes were assessed and found to correspond well with CRC practices at MSK.

CRCs: Key players in trial success

Gynet Santiago is a seasoned CRC at MSK, with 16 years of experience and involvement in over 50 clinical studies. She summarizes her role as, "I am responsible for collecting, extracting, and entering data for research projects, databases, and clinical trial protocols. This includes reviewing patient charts, existing databases, and other sources within a specific timeframe."

The CRC is pivotal in executing clinical trials, with responsibilities spanning various trial phases to ensure compliance with regulatory requirements and ethical standards, while prioritizing patient safety and data integrity. During trial execution, CRCs manage participant recruitment, screening, and enrollment, ensuring informed consent is obtained. They accurately collect and document clinical data, monitor participants for adverse events, and ensure adherence to the trial protocol. CRCs act as liaisons between participants, investigators, and sponsors, maintaining communication and addressing issues. They also ensure regulatory compliance by maintaining accurate documentation and assisting

EHR to EDC integration at Memorial Sloan Kettering

IgniteData

RESULTS

Implementing EHR to EDC delivered a reduction of time spent on manual data entry by 70%.

Future studies using Archer are expected to **reduce total study costs by over 20%.**

Sundgren, Mats, and Gynet Santiago. "Streamlining Clinical Trials with eSource: Insights from MSK." *Applied Clinical Trials*, vol. 33, no. 8, 19 Aug. 2024

The "MSK eSource use case" highlights the significant benefits of eSource technology and corroborate time metrics in supporting CRC and site personnel during trial execution.

EHR-to-EDC at Memorial Sloan Kettering Cancer Center (MSK):

A Retrospective Analysis of eSource-to-Sponsor Data Transfer Efficiency and Accuracy in Phase 1 and 2 IIT Studies

Richard Yeatman

Chief Operating Officer
IgniteData

IgniteData

Joe Lengfellner

Sr. Director, Clinical Research Informatics & Technology
MSK

Memorial Sloan Kettering Cancer Center

Traditional Data Capture

Increasing Number of Datapoints

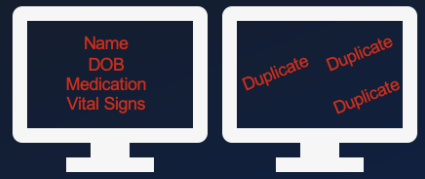
Currently approx. 15,000 per patient

Time Consuming

Estimated 3 minutes per datapoint

Resource Heavy

Validation requires at least x2 staff members



Error-Prone

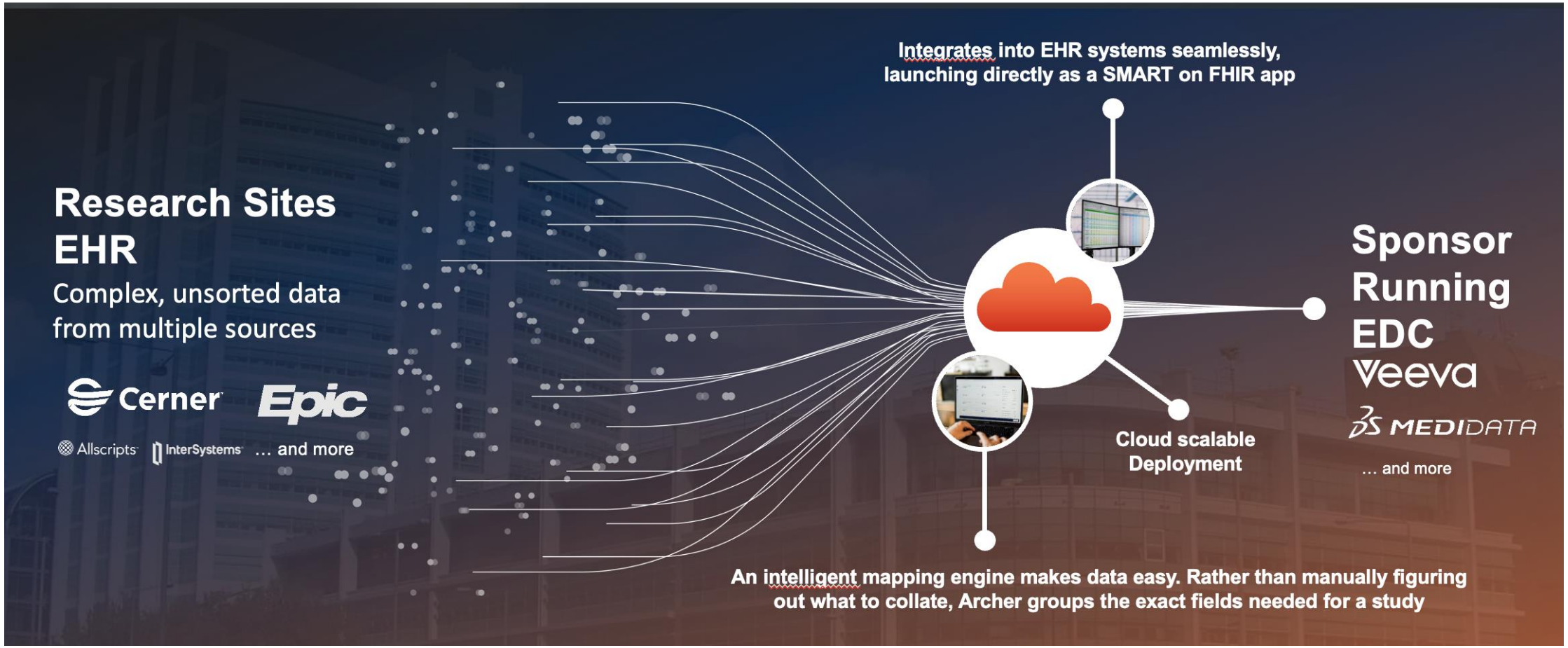
***70%** of clinical trial data is duplicated between EHR to EDC*
***8-10%** is manually entered incorrectly*

IgniteData

eSource

IgniteData

The Future of Data Integration

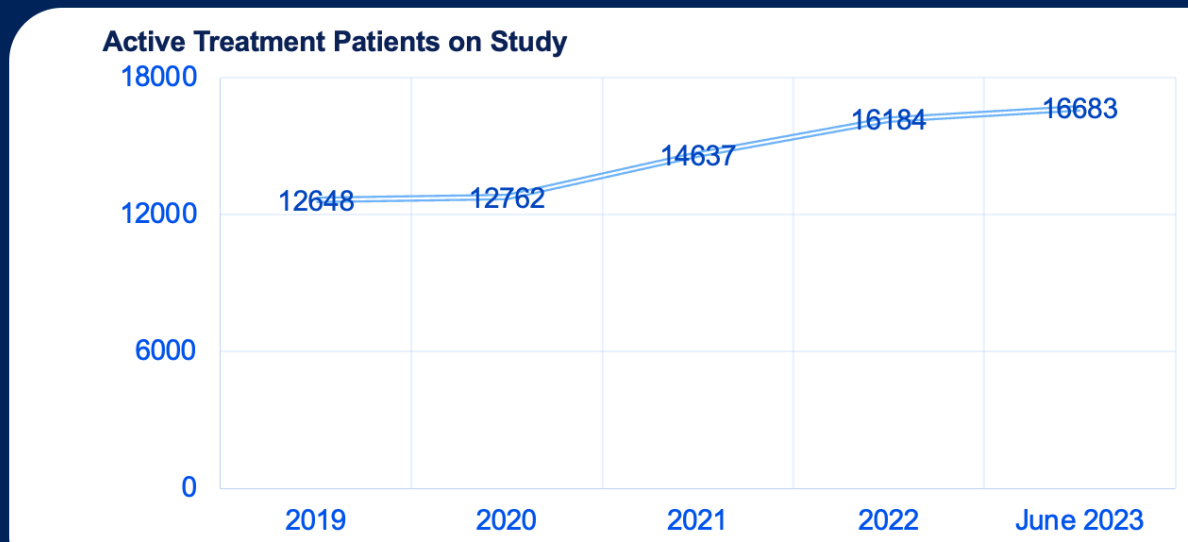


Key Data Domains

The Mounting Challenges Faced By Provider Sites Today

"What we're seeing is the consequence of biopharmaceutical companies engaging in more ambitious and customized drug development activity that targets a growing number of rare diseases, stratifies participant subgroups using biomarker and genetic data, and relies on more structured and unstructured patient data from a larger number of sources,"

Ken Getz, Professor and Director of Tufts CSDD

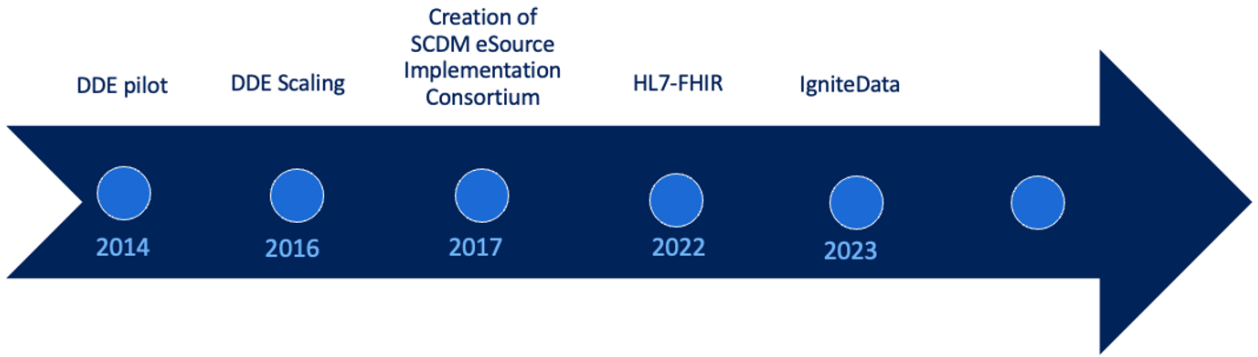


MSK's Experience Mirrors Larger Trends and Challenges:

- Increased number of smaller, targeted trials
- Clinical trial designs have changed, but the infrastructure to collect the data has not
- Trial Complexity is Increasing
  - Increased data requirements from sponsors
  - Increased queries from sponsors/CROs
  - More patient management activities
- Patients on study for longer
- All while managing industry-wide staffing shortages

Memorial Sloan Kettering Cancer Center

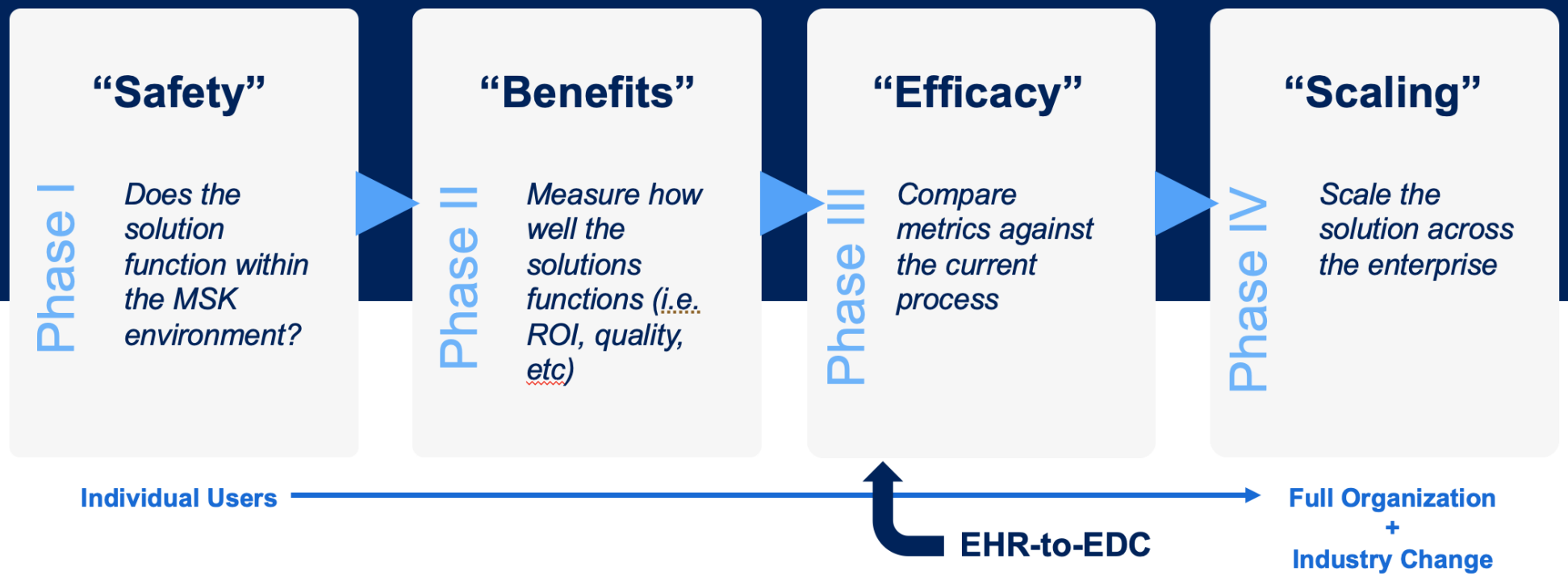
How MSK Is Proactively Tackling These Challenges



- Since 2016, MSK has electronically sent a million data records for both sponsored and investigator-initiated research
  - Numerous publications and presentations validating the methodology and value
- MSK Leadership has identified scaling EHR to EDC as a top priority
- Selected *IgniteData* as MSK's provider of EHR to EDC technology in a collaboration that took place within the MSK Innovation Hub
  - IgniteData's focus on site experience as a key determinant
  - Does not require a digital transformation at the site or sponsor level
  - Integrates seamlessly into existing EHRs, EDCs, and data lakes
  - Platform to be used for both sponsored and investigator-initiated studies

Memorial Sloan Kettering Cancer Center

How do we evaluate new technology initiatives?



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Study Design

Objectives

- Assess the speed and accuracy of the EHR- To-EDC enabled data entry method versus traditional, manual data entry.
- Assess user satisfaction with the platform.

Study	Phase	Disease Area	CRC Months of Experience
Study 1	I	Head & Neck	9 to 12
Study 2	II	Thoracic	More than 24
Study 3	II	Gynecology	More than 24
Study 4	II	Gastrointestinal	9 to 12
Study 5	II	Lymphoma	More than 24

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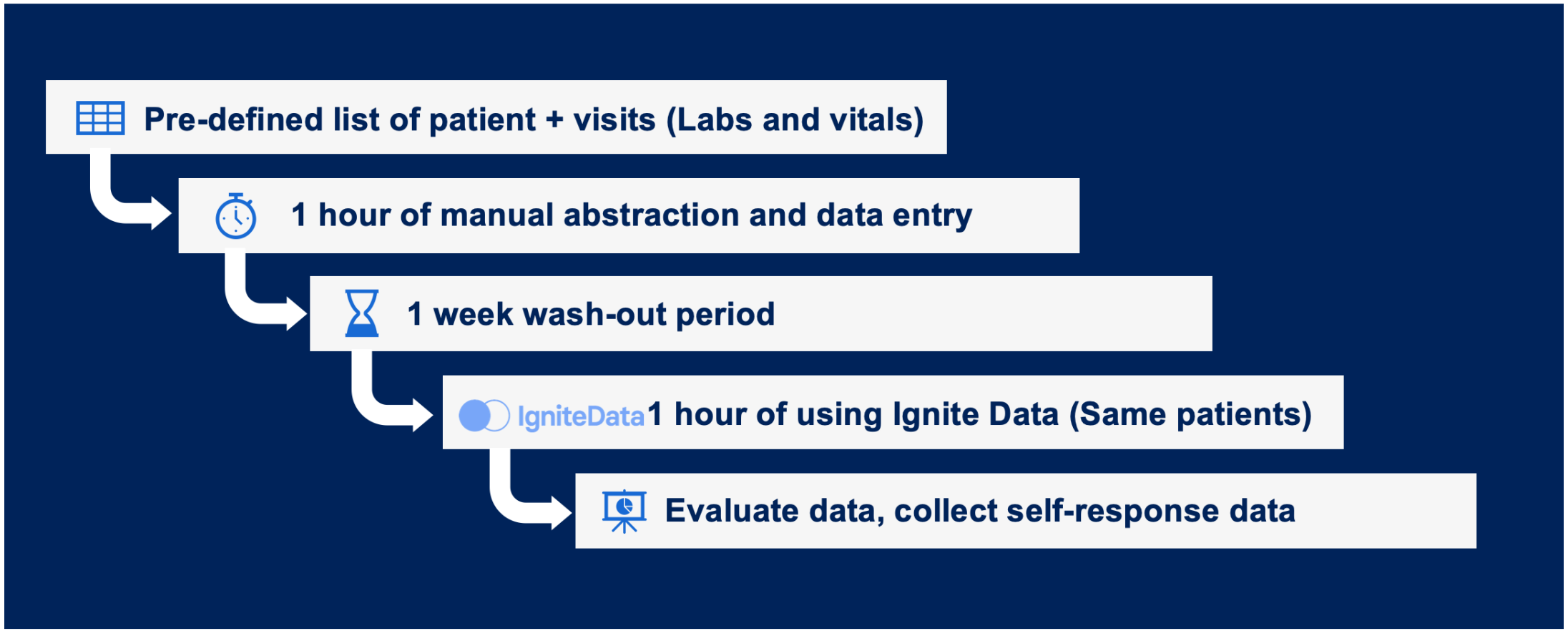
Methods



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Results – Data entry speed

Study	Manual	IgniteData	Difference %
Study 1	460	859	87%
Study 2	720	1059	47%
Study 3	526	749	42%
Study 4	931	1300	40%
Study 5	386	801	108%
Total	3023	4768	58%

Overall, the EHR-To-EDC method resulted in 58% more data entered versus the manual method (difference, 1,745 data points; manual, 4,768 data points; EHR-To-EDC, 3,023 data points)

Memorial Sloan Kettering Cancer Center

Results – Data quality

Field Count Type	Field Count	Manual Errors	Manual Error Rate (%)	EHR-To-EDC Errors	EHR-To-EDC Error Rate (%)
Study 1					
All Cases	859	10	0.022 (0.01, 0.04)	0	0 (0, 0.004)
Matched Cases	460	10		0	0 (0, 0.008)
Study 2					
All Cases	1059	33	0.046 (0.032, 0.064)	0	0 (0, 0.003)
Matched Cases	720	33		0	0 (0, 0.005)
Study 3					
All Cases	749	15	0.029 (0.016, 0.047)	0	0 (0, 0.005)
Matched Cases	526	15		0	0 (0, 0.007)
Study 4					
All Cases	1300	3	0.003 (0.001, 0.009)	1	0.001 (0, 0.004)
Matched Cases	931	3		0	0 (0, 0.004)
Study 5					
All Cases	801	39	0.101 (0.073, 0.136)	0	0 (0, 0.005)
Matched Cases	386	39		0	0 (0, 0.01)

Memorial Sloan Kettering Cancer Center

Results – Clinical Research Preference

	Average Rating (n=5)
Archer's electronic transfer workflow was easy for me to learn.	5
It was easy to transfer data to the EDC using Archer.	4.6
Transferring data through Archer is less time consuming than entering data manually.	5
Transferring data through Archer is more efficient than entering data manually.	4.8
I prefer transferring data electronically with Archer over manual data entry.	4

User satisfaction results (Rating scale, 1= strongly disagree, 2= disagree, 3= neutral, 4= agree, 5= strongly agree).

Memorial Sloan Kettering Cancer Center

Discussion/Conclusion

Advantages

- **Using EHR-to-EDC, data was entered more quickly, was of a higher quality, and preferred by CRCs**
- Minimal training curve to using the technology
- Low technical barrier to entry, easily scalable to multiple studies

Limitations

- Currently, focused on structured data

Innovating at Scale: A Dual Strategy

For MSK

- Working towards scaling to our full portfolio
  - Four large sponsors
  - Investigator initiated portfolio
  - ~ 30 live studies
- Evaluating NLP/LLM pipelines to aid with the unstructured data
- Continued advocacy with sites/sponsors and CROs

For the clinical trial industry

- No more pilots, it works
- Consolidate on standards (i.e. FHIR) to help scale. Work with industry partners
  HL7 – Vulcan
  The European Institute for Innovation through Health Data (iHD) – eSource for Scaling Up Clinical Trials
- Encourage partnerships between research sites/hospitals and sponsors to drive clinical trial innovation

Memorial Sloan Kettering Cancer Center

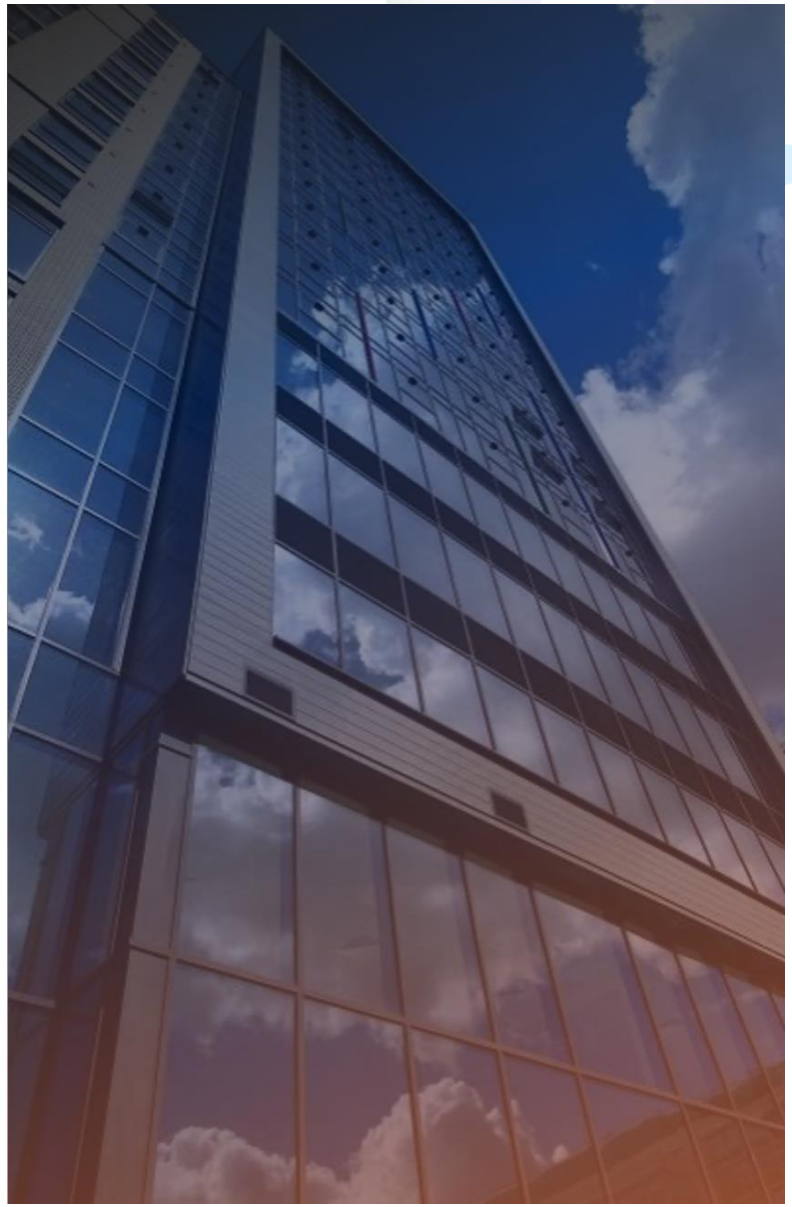
Driving Clinical & Operational Impact

99.999%
Data Accuracy

87.15%
Reduction in Queries

6.8x
Faster Data Access

IgniteData



SCDM Live

Bridging the Gap

Bayer's EHR-to-EDC Integration Journey

Stephan Cichos

Strategic Project Leader,
Clinical Data Strategy & Operations, Bayer AG

Agenda

1. Our Motivation
2. The Need for Change
3. Implementation Journey
4. Next steps and future direction

Our Motivation

01

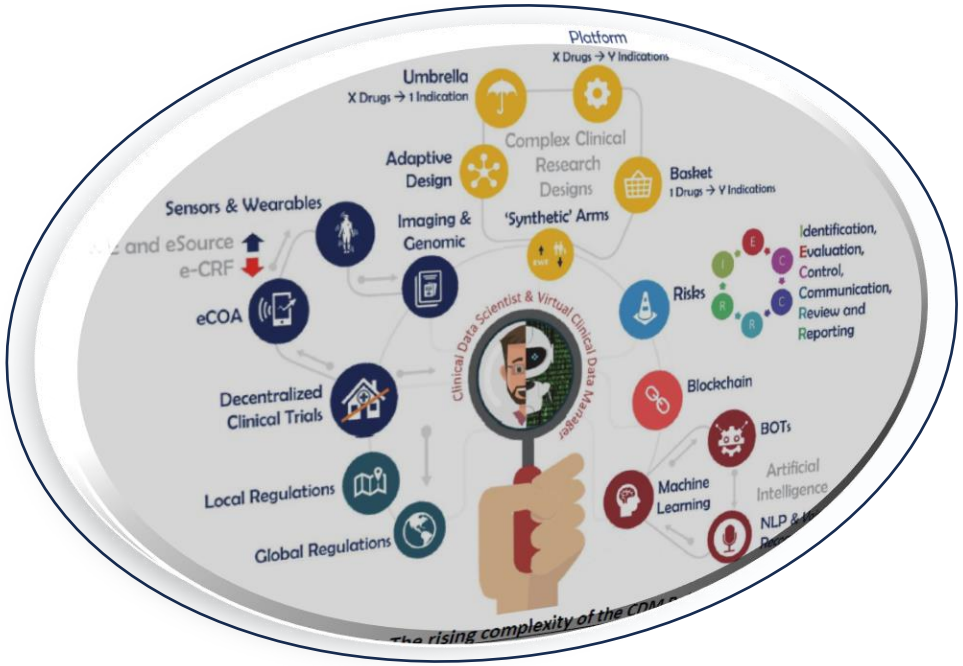
Our CDM Community's Purpose and Motivation

Purpose

With a **customer-centric** mindset, we provide **fit-for-purpose data** from clinical studies as a foundation for developing **better therapies** for **patients in need**.

Towards CDS with a Customer Centric Mindset

Increasing Complexity will not just only challenge CDM…



**SCDM Reflection Paper "The Evolution of Clinical Data Management into Clinical Data Science"*

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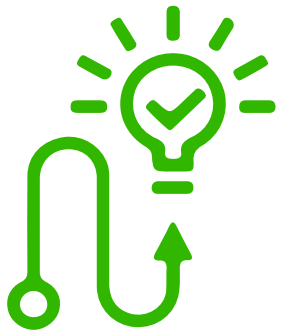
?

but also Sites too…

**GPT-4o mini*

We strive to be advocates for our sites & patients

How

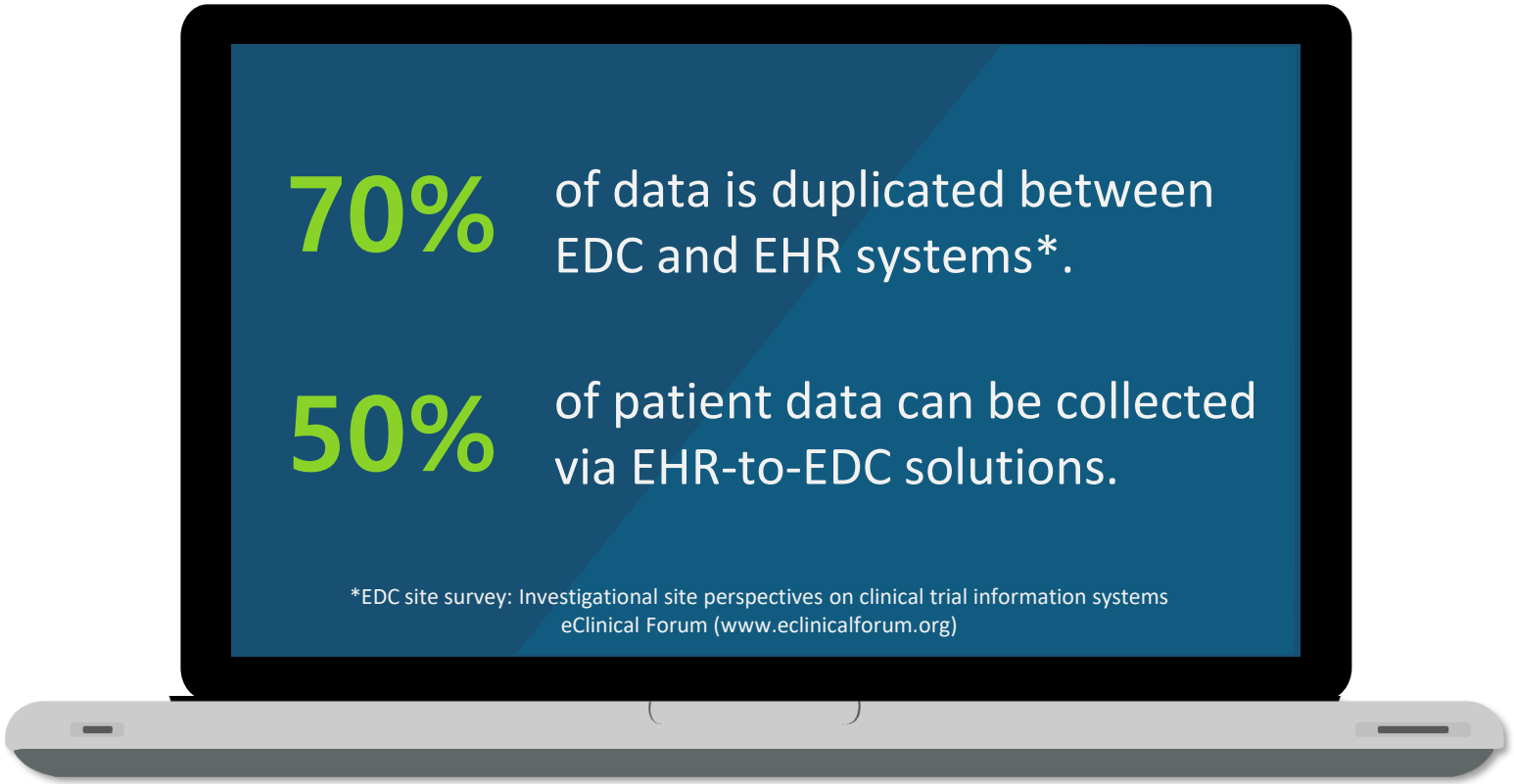


- Being **actively involved** in early-stage discussions contributing to study strategy and execution decisions.
- **Evaluating** potential **challenges** and **risks** associated with data collection and management.
- Aim to **minimize** site **workload** and enhance data accuracy.
- **Empower** sites, ensure they feel **valued** and **equipped** to **manage** the **complexity** in clinical studies.

The Need for Change

02

Manual effort transcribing duplicated data result in Increased Workload, Higher Error Rates & Decreased Efficiency



Effort for Manual Data Transcription

3
minutes effort per data point*

*Including source data retrieval, data entry, SDV, queries and corrections

Streamlining Data Collection: Automated Flow from Sites' EHR Systems to Bayer's EDC System

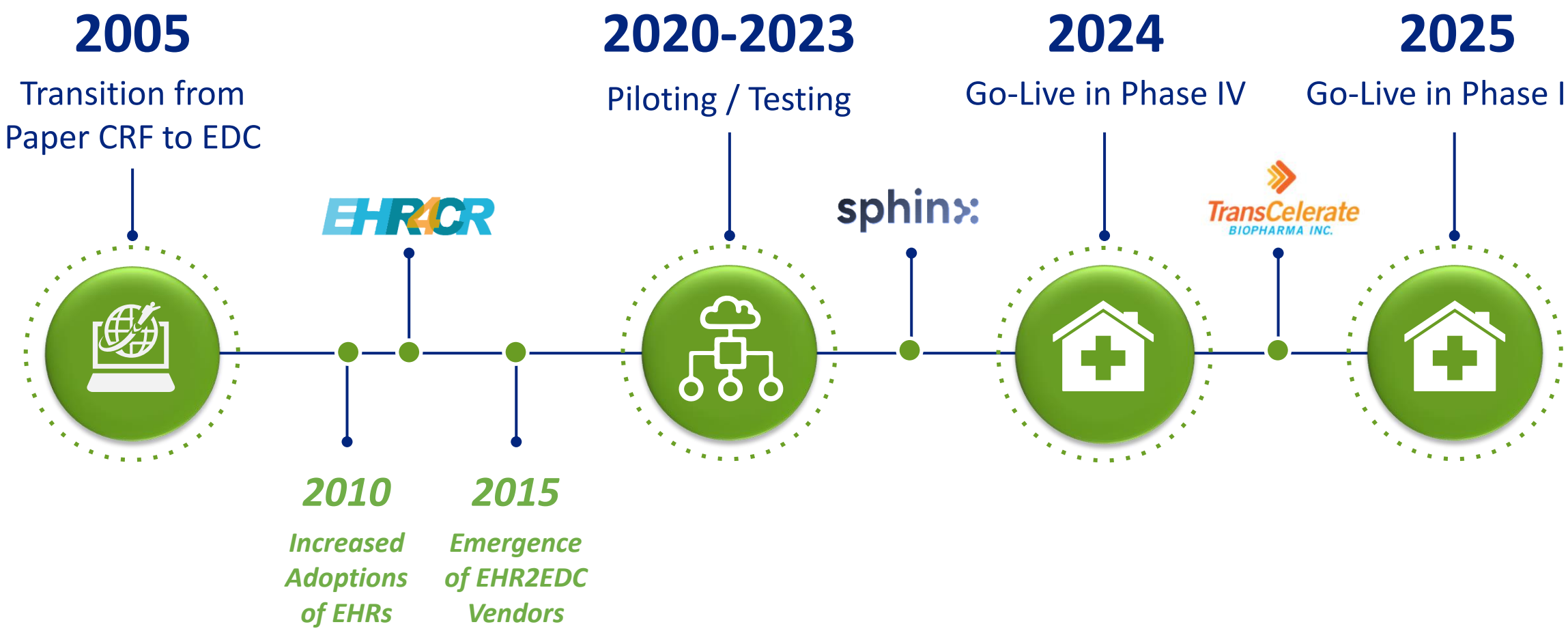
// Less Manual Data Input / Re-entry
// Less Volume of Query Management
// Less Transcription Errors

Workload Reduction: ***Allowing Sites to Focus on What Truly Matters!***

Implementation Journey

03

Our journey so far



From Exploration till Go-Live of EHR-to-EDC

- Clinical Data Management
- EDC Developer / Integration Experts
- CRAs (Site Management)
- Study / Project Management
- IT Quality Assurance, GxP IT Experts
- Vendor Management / Procurement
- Relevant SOP Owners

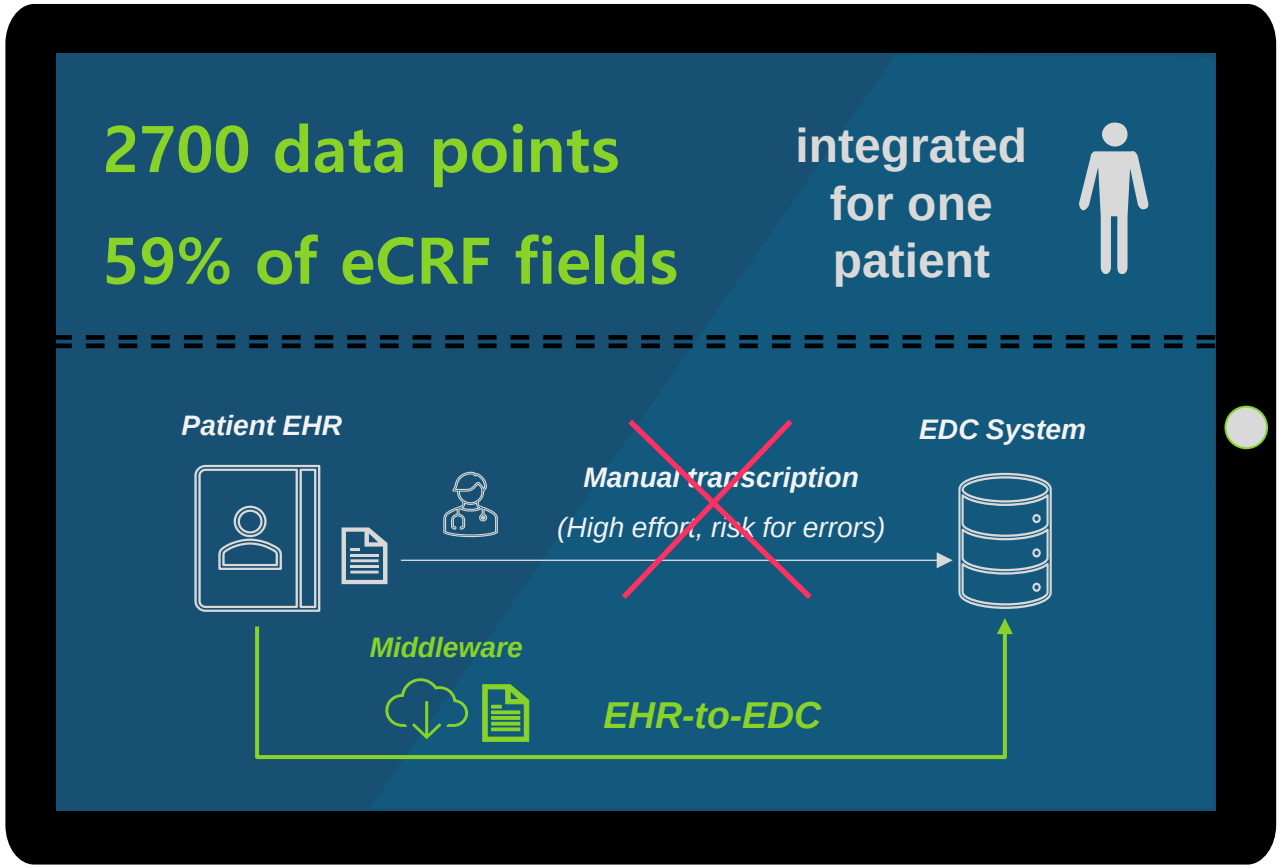
*GPT-4o mini

Defining Technology & Vendor Evaluation Criteria

- EDC compatibility
- Robust scalable mapping engine
- Existing / Future site network
- GxP compliance e.g. focus on SDLC
- User interface
- Ease of implementation
- Site training & support

*GPT-4o mini

Simulating an EHR-to-EDC Data Integration



Simulation parameter

- 10 Cycles (incl. Day 1, Day 8, Day 15)
- Screening, End of Treatment, Follow Up
- Vital Signs Forms
- ECG Forms
- Local Lab Forms
- One Unscheduled Visit

Vendor- and Technology Qualification Activities

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

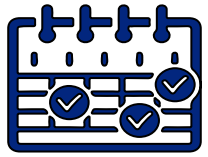
07 April 2020
EMA/INS/GCP/467532/2019
Inspections Office, Quality and Safety of Medicines Department

Notice to sponsors on validation and qualification of computerised systems used in clinical trials

Note: This notice should be read in conjunction with Q8 and Q9 from the good clinical practice (GCP) Q&As published on the EMA website:
https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/qa-good-clinical-practice-gcp

- Business reliability
- Policies and quality procedures
- Effectiveness of current process
- Software Development Life Cycle
- Change management
- User Management
- ....

Define Early Adopter Criteria

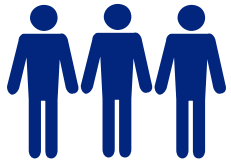


Timing / When

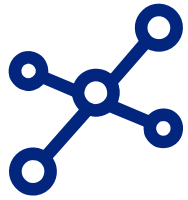
EHR systems

Sites **Location**

Sites **accept usage**



Number **Patients**



Data in scope

Next steps and future direction

04

What's to come: Next steps and future direction

Ecosystem of sites with EHR-2-EDC expanding

EHR-2-EDC as default offering

>50 % Datapoints integrated

EHR-2-EDC Integration Assessment

SOPs / BPDs adapted

Playbook for EHR-2-EDC Integration

Present Learnings & KPIs at next SCDM ☺

Measure Success of Early Adopter Studies

Thank you !

Happy to connect and to exchange!

Q&A Panel

Closing

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