VISION FOR EHR-TO-SPONSOR DATA INTEGRATION

Dr. Dawn Bardot, GM Global Service & Cloud Product, Abiomed

Dan Housman, Chief Technology Officer, Graticule

TODAY'S PRESENTATION

Dawn Bardot, PhD
GM Global Service and Cloud Product, Abiomed

- Background in medical device innovation and digital health.
- Intrapreneur at Abiomed encompassing global field service and sales, remote monitoring platform Impella Connect and AI Software-as-a-Medical Device portfolio.
- Former Innovation Director at Medtronic and VP of Innovation at Medical Device Innovation Consortium, a public/private partnership between the FDA, patient groups and medical device industry.

About Abiomed

- Leading provider of medical technology that provides circulatory support and oxygenation, acquired by J&J (2022)
- Founded 1981 with the purpose to develop world's first artificial heart
- 18+ year strategic focus on heart recovery therapies (blood flow, oxygenation for respiratory failure patients)

Dan Housman
Chief Technology Officer, Graticule

- Background in real-world data, interoperability, and clinical analytics
- Co-founder of *Graticule* and *Recombinant Data*
- Former CTO of healthcare analytics for *Deloitte*

About Graticule

- On-demand real-world data and advisory services provider
- Founded in 2018 by Dan H and CEO, Dan Poscover
- Innovation focus on data resource optimization for neurology, cardiology, oncology and rare disease clinical research

Solving RWD and Process challenges in Trial Design and Execution

Improve patient screening and identification for trial eligibility

Current practice: patients who may benefit from PCI procedure are overlooked

Patient ID solution

1. Intelligently mine structured and free form (notes, images) EHR data
2. Identify cohorts of eligible patients
3. Perform advanced screening to qualify and prioritize eligible patients for trial

Health System Users

450+ bed, NJ-based
Adopted: 9/2023

750+ bed, Louisiana-based (Non-Profit)
Adopted: 8/2023

1,000+ bed, Alabama-based
Q1/2024

1,300+ bed, Florida-based
Q1/2024

ABIOMED

graticule

Recent innovation projects include patient recruitment and EHR-to-sponsor connectivity to improve research data sets and accelerate research processes

Optimize clinical trial data collection and delivery

CLEHR

EHR to Sponsor Integration

STAFF BURNOUT AT SITES IMPACTS RESEARCH STUDY PARTICIPATION AND SCOPE

Clearly, the industry hasn't focused on site workflows and the negative impact on clinical research operations …

- Erik Kroeker, Data Engineering/Analytics Manager

Manual entry into EDC forms:
Time-consuming, error-prone activity done by busy CRC specialists

Outcomes example: Understanding *cause and effect* to satisfy study requirements

Need a BP baseline (pre treatment)
CRC searches/compares all BP values to find highest baseline

Need highest creatinine < 72 hours (post)
CRC searches every single value, and cherry picks the "right" one

CRC search and selection of key values with hope they are accurate and representative

Burnt out staff
Poor use of valuable resources
Impacts site ability to participate in study

THE PROCESS ALSO CREATES RESOURCE WASTE FOR SOURCE DATA VERIFICATION

Form-based data transfer between health system EHRs and sponsor EDC (Electronic Data Capture) environments is inefficient and severely limited

Status quo: Example from cVAD Registry

- Ongoing FDA study since 2009
- ~5,000 subjects captured
- All pumps placed at active sites
- Subjects followed for one (1) year

Quality Control Management

June 2017 to December 2020

Site X was queried >1,400 times to resolve discrepancies (SDV) of discrete data fields entered into the cVAD EDC.

(i.e., Admit/discharge date, lab values, gender, weight, medications, etc.)

↓

Resolution of a single query takes ~10 minutes

↓

1,400 queries × 10 = 233 hours
(29 work days)

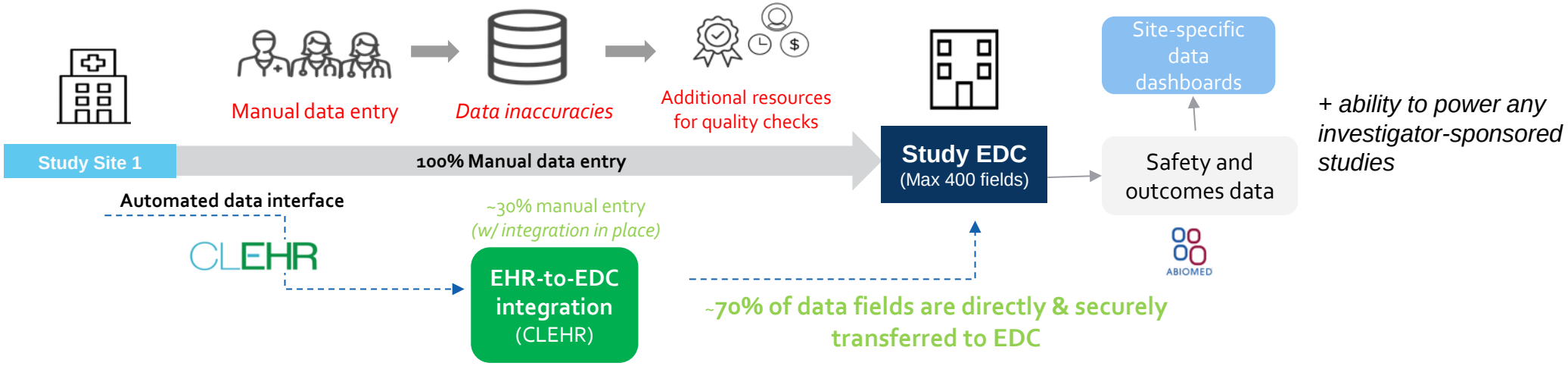
Lost productivity & poor use of valuable resources

INTRODUCING A UNIQUE, CENTRALIZED APPROACH TO DATA COLLECTION

CLEHR

Integrates EHR-to-Sponsor data transfer to reduce the complexity of data extraction/collection.
Expands data sets for a truer, more accurate picture of patient condition
Centralizes and **automates** the function for better data with far less effort

CLEHR removes data management responsibilities from the hands of the sites



- **Frees sites from the burden of local field mapping**
- Directly interfaces with EHRs to extract records for patients in research studies
- Automates 70% of data entry – no errors, time and cost savings

- Goes beyond limits of EDC forms, broader data sets, greater volume and frequency, supports insights such as trending
- Honest broker solution - SaaS-based
- Independent and compliant infrastructure

FHIR-BASED CONNECTIVITY TO EHR DATA ELIMINATES LOCAL SITE FIELD MAPPING

EHR-to-EDC environment integration eliminates the need for labor-intensive, error prone manual data mapping at participant sites

Standardized USCDI v1 and FHIR data modules allowed Abiomed to map EHR data elements to the EDC data dictionary so the sites/clinics don't have to

Health System EHR

USCDI v1 FHIR

Patient-specific data exports

Standard FHIR data modules

- Demographics
- Medications
- Lab Chemistry
- Medical History
- Vital signs
- Others…

Pre-mapped

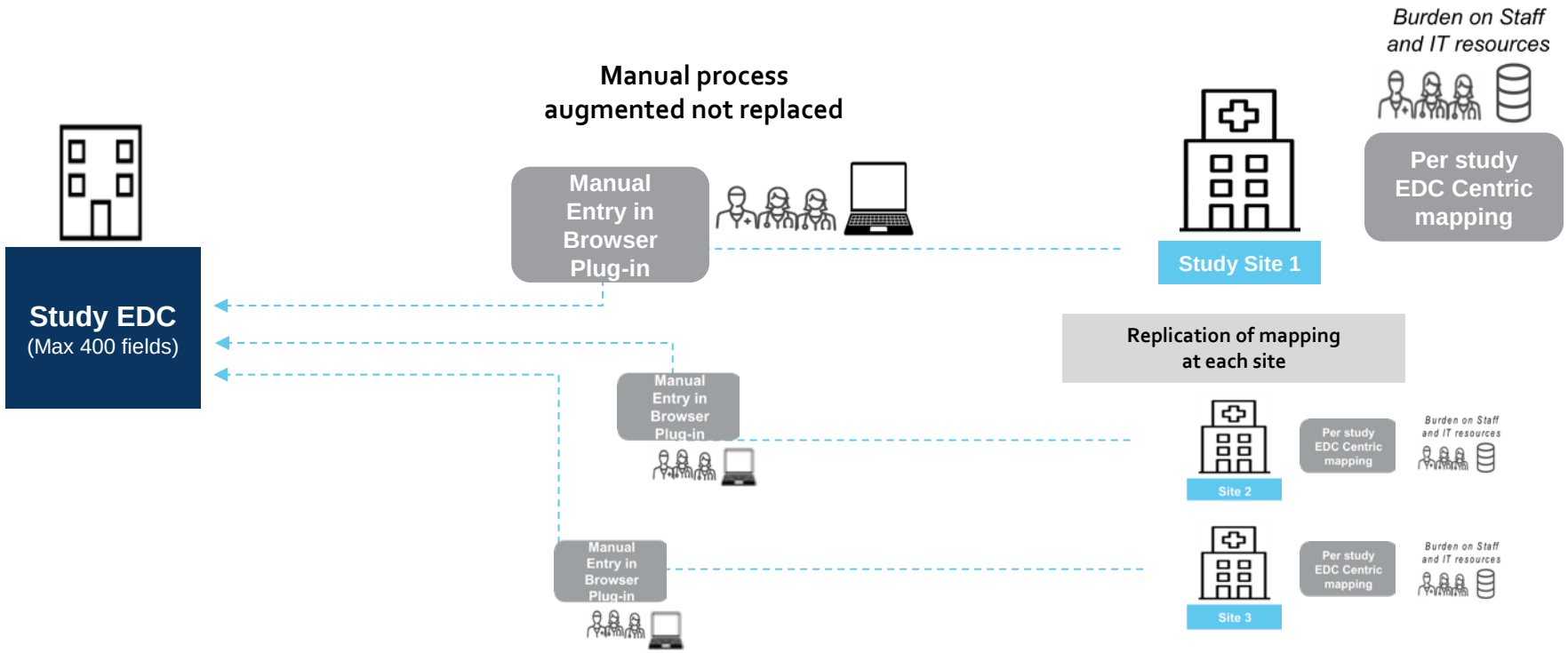
MEDIDATA | Rave

No local Site EHR to EDC field mapping is required

GAP ANALYSIS: EDC-CENTRIC TOOLS AUGMENT DATA ENTRY WITH PER SITE IT MAPPING

Existing EHR-to-EDC tools on the market today

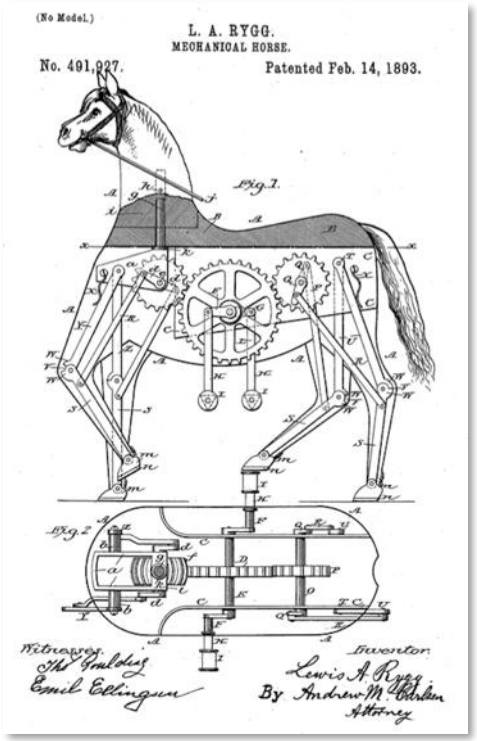
- Simply help to manually populate EDC forms
- Clinical Research Coordinators still face labor-intense work
- Limited to form fields - do not expand or diversify the data available to the sponsor
- Poor support for valuable, correlated-in-time values like labs



Tools do not solve the site burden problem – rather, they slightly improve manual processes

A LIMITED VALUE PROPOSITION: DIGITAL VERSIONS OF *PEN AND PAPER* FORMS

Example of EDC data transfer tool



EHR Mapping Helper

The Mapping Helper utility will assist you in finding the fields in your EHR (electronic health record system) that you would like to utilize in your Clinical Data Pull project or Clinical Data Mart project. If you already have appropriate privileges for pulling data into REDCap from your EHR, you may enter a valid MRN (medical record number) into any of the tabs in the Mapping Helper to pull all the data for that patient for those data categories. Once the data is pulled, it will be displayed on the page for you to view. The EHR field names and LOINC codes will be displayed, thus allowing you to find the specific fields you need to use during the field mapping process of your CDP or Data Mart project.

Please note

Dates returned by FHIR systems are in Zulu military time.

Where applicable, the Mapping Helper will provide a "local" timestamp reflecting the timezone of the REDCap server (US/Central).

Home | Custom request

MRN: 201688 | Date from: mm/dd/yyyy | Date to: mm/dd/yyyy

Fetch 22 resources

Wensel A Identity

Total entries: 123

FHIR ID: enUzUbclL5CmKODptMHj-iw3

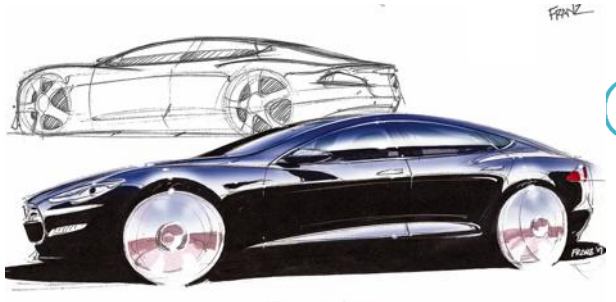
Gender: M **DOB**: 1970-02-24 **Age**: 53

Rotate results | Mapping status | search... | Show payload

Allergy Intolerance | « ‹ 1 › » | Per page: 25

Mapping status	fhir_id	recorded_date	normalized_timestamp	clinical_status	text	ndf_rt_display	ndf_rt_code	f
MAPPED	e3LPIrqsWgv0wPxb69Nqj-w3	2010-08-14T05:00:00Z	2010-08-14	Active	BEE VENOM			

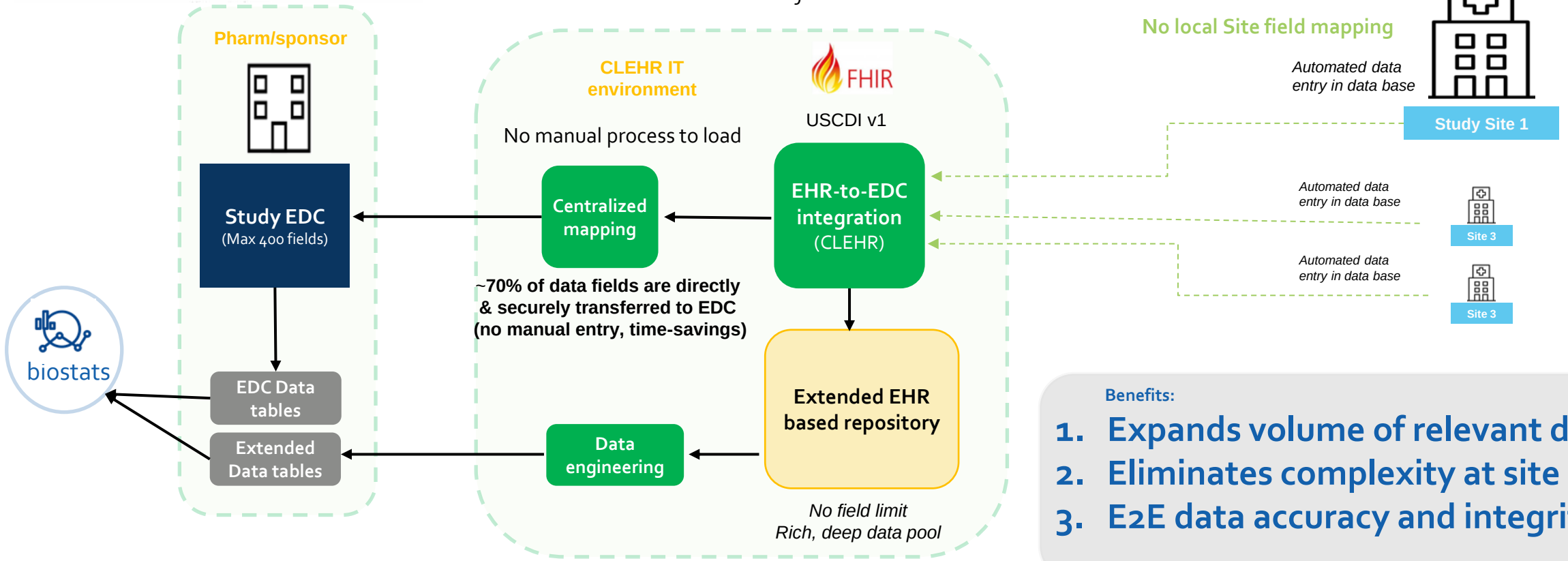
CLEHR VISION: BREAKING FREE FROM THE CONSTRAINTS OF EDC FORMS



CLEHR

Data transfer automated within a single system connects rich relevant data from the EHR to sponsor EDC environments

Access to rich, high-volume data not possible with limits of EDC-based data transfer



Benefits:

1. **Expands volume of relevant data**
2. **Eliminates complexity at site level**
3. **E2E data accuracy and integrity**

CLEHR IMPACT: THE RICH DATA SETS RESEARCHERS ALWAYS WANTED

Finally, we have easy access to the full data sets we've always wanted for our studies, but couldn't get without all the back and forth with sites …"

–Erik Kroeker, Data Engineering/Analytics Manager, Abiomed

> We have broken the constraints on how much important data we can ask for …

Results

CLEHR

With our 1st LOQI study patient alone, we had almost 3,826 data points – impossible with manual CRC form entry.

If I were to ask staff to enter this data into EDC forms – we would get 30 data points, not 3,826.

Now, CRCs do not have to search and cherry pick representative values and hope it is a correct representation …

> Everything is **validated from the source** … with no human hours spent checking data points for accuracy

CLEHR IMPACT: A MORE COMPLETE CLINICAL PICTURE OF EACH PATIENT

Granular and relevant data
not limited to EDC form fields

291 **BP measures vs only 2 with EDC**

Supports trending analysis and patient safety

360
Tracked patient encounters vs. EDC tracking of re-admission only

Observation	Count
Pulse	437
SpO2	423
Resp	396
Temp	339
Systolic blood pressure	291
Diastolic blood pressure	291
POC Glucose Monitoring	87
WBC	45
Weight	44
eGFR CKD-EPI 2021	44

CLEHR IMPACT: IMPROVED RESEARCH VIA DATA ACCURACY AND FLEXIBILITY

Flexibility with the data

EHR-to-Sponsor data supports advanced statistical analysis for clinical research. The data set provides a truer picture of patient condition and can be curated in different ways by researchers.

Expanded, relevant data sets

Granularity to make better clinical decisions

Available on-demand to the sponsor

Easily curated to study protocols, timeframes or other selected constraints for statistical analysis

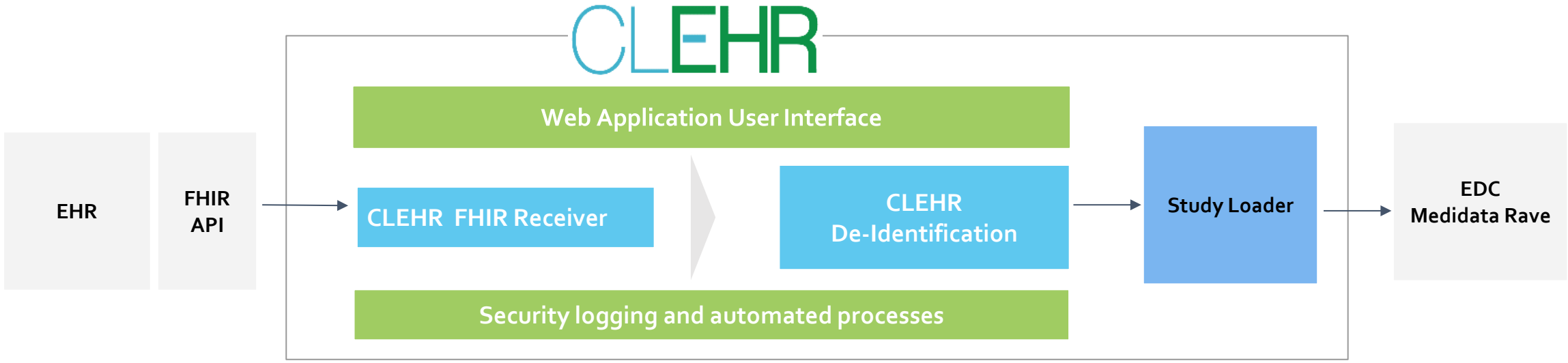
Confidence in the data

Direct integration with the site means data is validated back to its source – data quality and integrity is guaranteed E2E.

Focus on statistical analysis, not data collection and QA ✓

Sponsors and sites are freed from data collection workloads to focus on high value research activities, with richer data sets to improve research quality.

CLEHR ARCHITECTURE: OPEN STANDARD AND SECURE



FHIR

USCDI v1

USCDI V1 and FHIR Based

The tool extracts data from the EHR system using open standard FHIR (Fast Healthcare Interoperability Resources). The CLEHR FHIR integration framework is used to scale the solution.

Policy engine that matches the study protocol

Appropriately de-identified patient data
Honest broker contractual relationship
Data time windows, volumes, and follow-up or refresh set to comply with study design

CLEARDATA

aws

Security and Compliance

Hosted on a secure cloud environment
Implemented controls for HIPAA and HITRUST using ClearData compliance management software

HOW IT LOOKS FOR CRCs

CLINICAL RESEARCH COORDINATOR: NEW CASE INITIATION

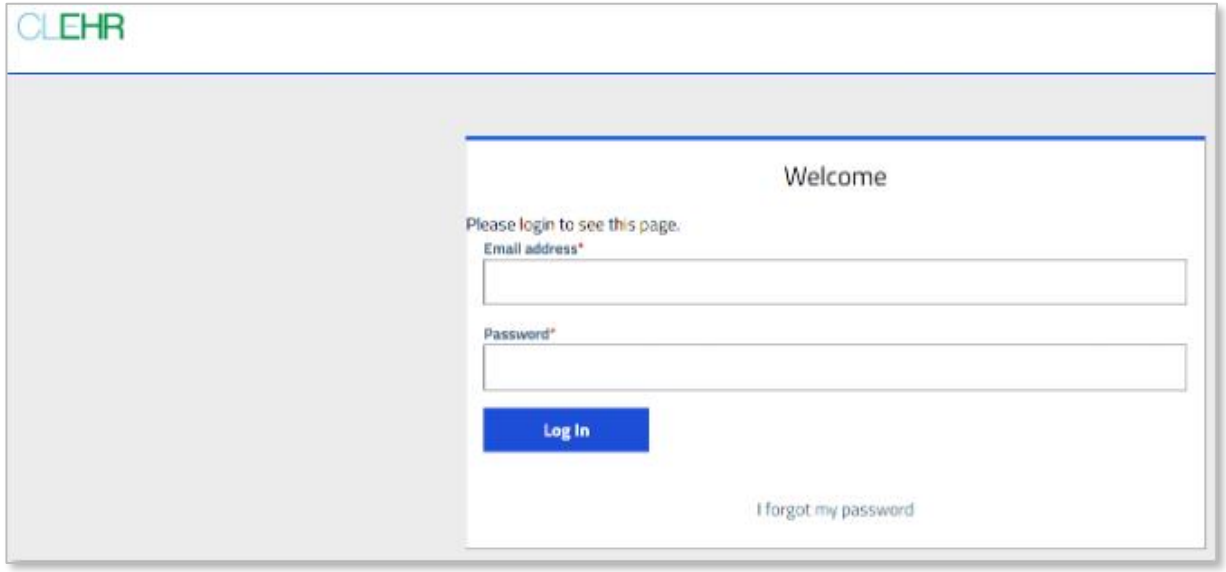
DEMO The following section outlines how sponsor stakeholders use the automated CLEHR tool to authenticate and link a subject to the clinical study.



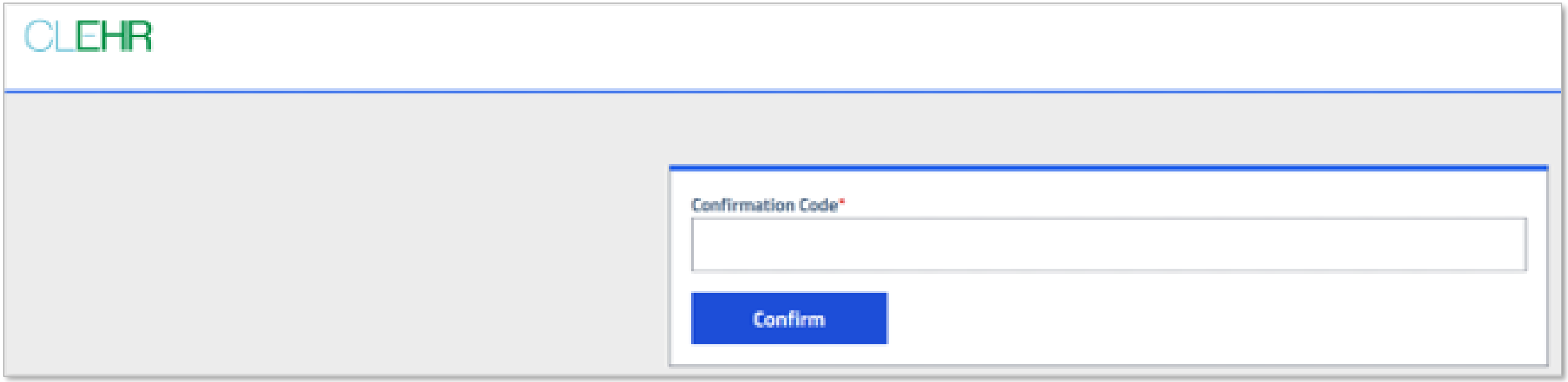

Impella pump supported patient	Abiomed identifies Impella use	Subject Creation	Subject Identification
Impella pump used at Study site	Impella Quality Database + Impella Connect	Abiomed Creates Study Subject in EDC (LOQI)	Abiomed notifies CLEHR of new subject added to EDC system

Clinical research Coordinator: Secure login

CRC Notification	Clinical research coordinator (CRC) at health system receives notification and logs into CLEHR

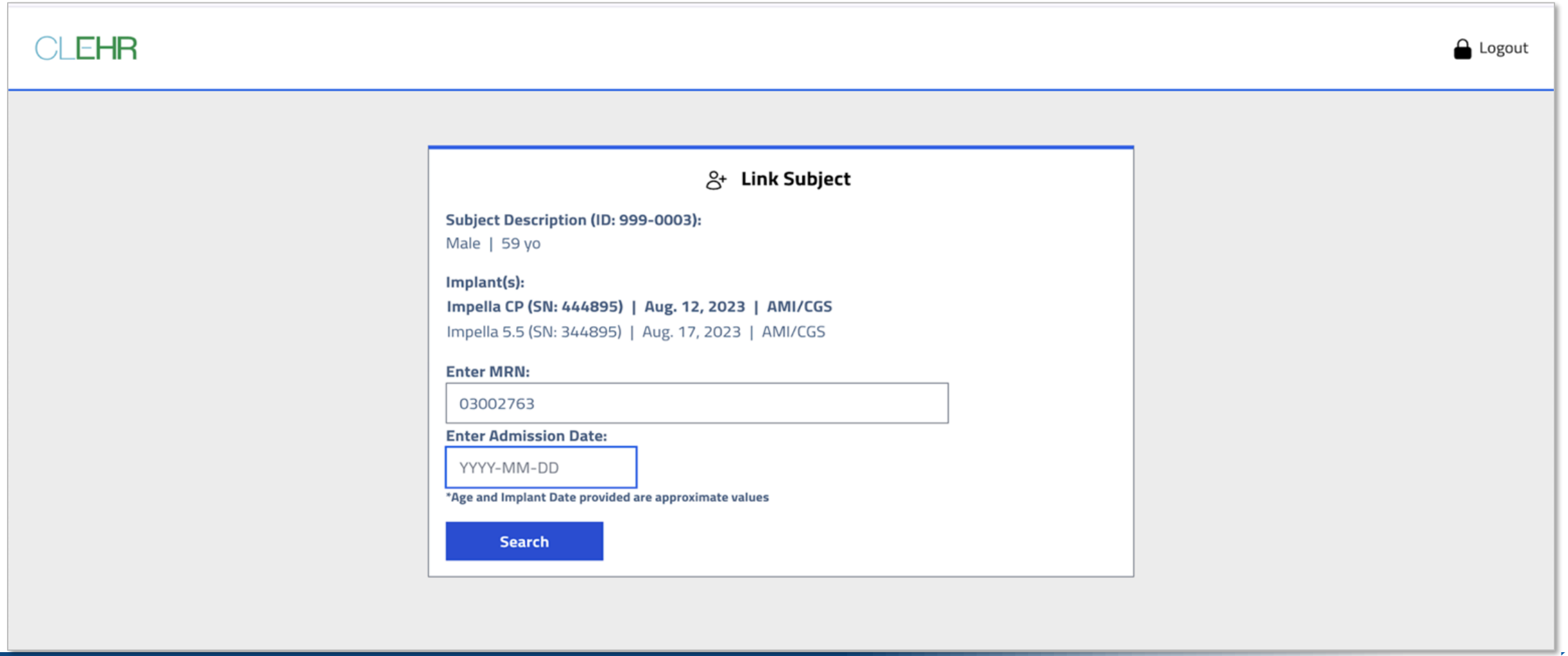


Two-factor authentification



CLINICAL RESEARCH COORDINATOR: CRC NEW CASE ADJUDICATION

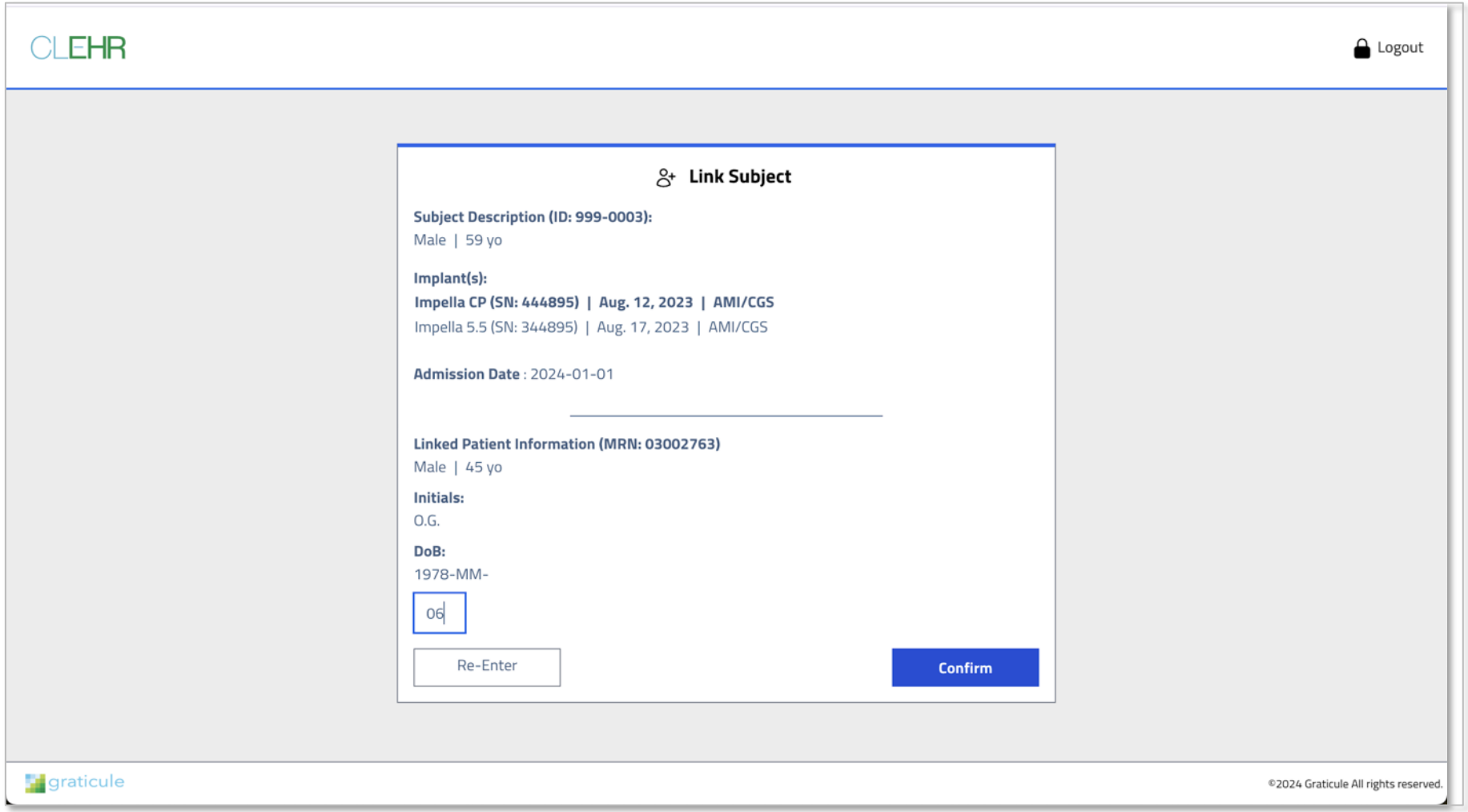
Subject Selection	CRC selects pending subject, enters the patient MRN & admission date



Clinical research Coordinator: New case confirmation

CLEHR returns de-identified data from the EHR

Subject Confirmation	CRC enters DOB and subject is linked to study, CRC is returned to subject listing overview



One minute of work per patient to deliver great results

Staff engaged and Empowered

More value with less work

Free to work on higher value research tasks

Preserves patient privacy

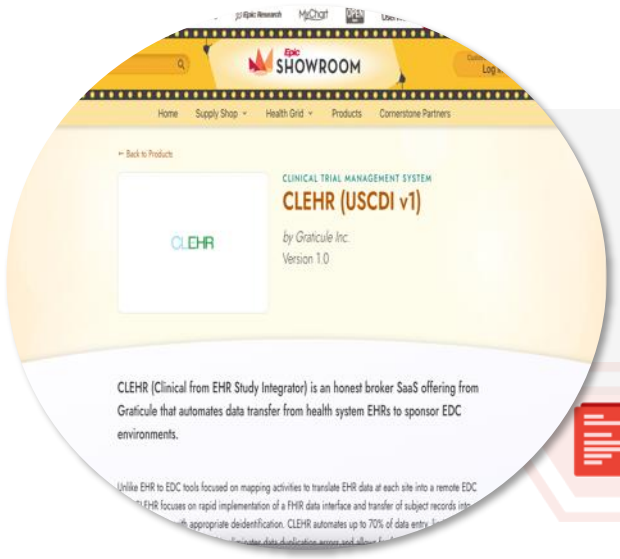
Manages quality

UP AND RUNNING: MILESTONES IN THE ROLL OUT OF CLEHR TO DATE

Setup and onboarding processes

Contracting, BAA & Other Pre requisites ✓

Implementation, testing, validation and GO Live ✓



Live in Epic Showroom

Following the 1st implementation, CLEHR was validated for the Epic Showroom marketplace (Dec. 23)

Sites onboarded for LOQI Study with CLEHR

Live integration ✓

550+ bed, Oregon-based
October 2023 ✓

October 2023

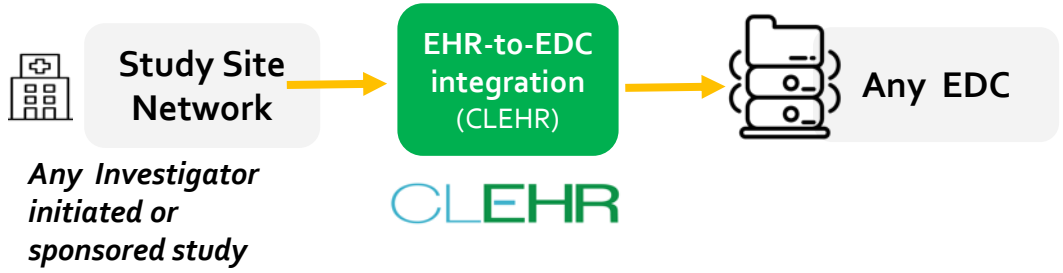
370+ bed, Ohio-based
December 2023 ✓

870 + bed, Michigan-based
Q1 2024

620+ bed, NJ-based
Q1 2024

Expanding to 20 sites in 2024

EHR-to-Sponsor scales to many studies and sites beyond LOQI



Any Investigator initiated or sponsored study

Abiomed

LOQI study

Abiomed

- *Door to Unload*
- *Protect IV*
- *Recovery 4*
- *IMPACT*
- *ECP*
- *PreCARDIA*
- *Low profile sheath*
- *RP Flex*
- *More…*

Johnson & Johnson

- *MedTech*
- *Acclarent*
- *Biosense Webster*
- *Cerenovus*
- *DePus Synthe*
- *Ethicon*
- *Mentor*
- *J&J Vision*
- *Pharma*
- *Jannsen Biotech*
- *Jannsen Vaccine*

Expansion to other Industry Sponsors

(MedTech and Pharma)

A RESEARCH NETWORK WITH ACCESS TO MILLIONS OF PATIENTS

Graticule Research Network

Health Systems

Baylor Health Care System
I.R.C.C.S. Ospedale San Raffaele
Northwell Health
Hackensack Meridian Health
BJC HealthCare
CommonSpirit
Università di Pavia
Memorial Sloan Kettering Cancer Center
City of Hope
GUSTAVE ROUSSY CANCER CAMPUS GRAND PARIS
VANDERBILT HEALTH
Cancer Treatment Centers of America
Atrium Health Wake Forest Baptist

Our health system relationships help us build specialized networks such as **Graticule Oncology Network** and **Graticule Covid-19 Network**

Aggregators

Partner Networks	1	2	3	4	5
Patient Volume	35M+	15M+	70M+	250M+	~17M
Member Hospitals	30+ Health Systems (+500 hospitals, +3700 individual facilities)	20+ Health Systems	14+ Health Systems	120+ Healthcare partners globally	77+ Hospital Partners
Data Type Availability	Mix of inpatient and outpatient care with structured and unstructured clinical data	Longitudinal records of structured and unstructured data	Full patient medical records linked across providers with mortality, comprehensive SDOH, and claims	Advanced patient data like EHR records, date- and patient-indexed clinical observations, genomics data	Structured EHR data

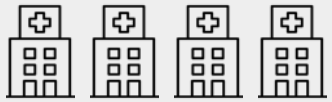
Data partners include

BIOMERIS, AURORA DIAGNOSTICS, PointClickCare, INVITAE, TRUVETA, NTT DATA, DEEP 6 AI, labcorp, TriNetX, LOOPBACK ANALYTICS, Arcturis Advancing Insights, inspire together we're better

EHR-to-sponsor is a paradigm shift for the Industry

EHR-to-Sponsor frees sites from significant workloads and provides the rich data sets researchers need

Clinical Sites



- No local site field mapping
- Free staff of unnecessary manual labor - engaged, empowered
- Break barriers to study participation

Accelerated trial planning and execution, faster innovation time to market

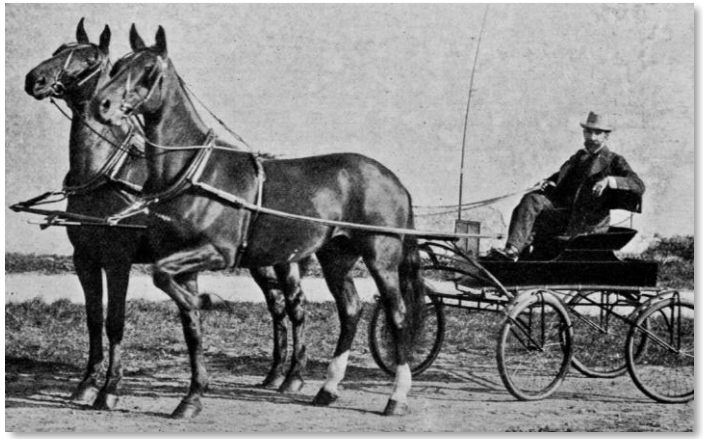
Research Sponsors

ABIOMED

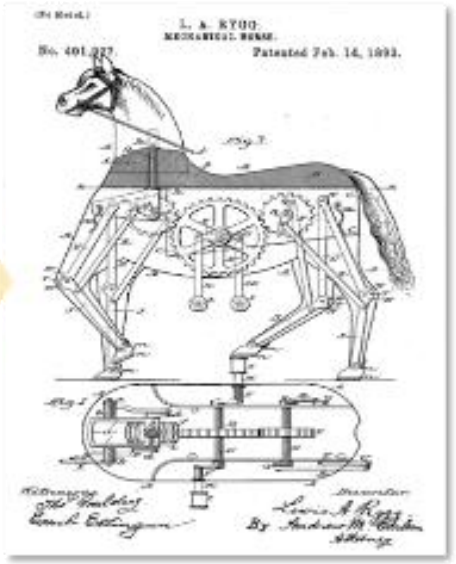
- Granular, high volume, accurate data beyond EDC form limits
- Greater analytical capabilities
- Supports site participation

Richer outcomes and safety data available on-demand for current and future studies

WILL EDC SYSTEMS BE SIMPLER OR GONE ONCE EHR TO SPONSOR BECOMES THE NORM?



EDC



EHR to EDC

CLEHR

EHR to Sponsor integration

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Q&A