graticule™

CLEHR: Clinical from EHR

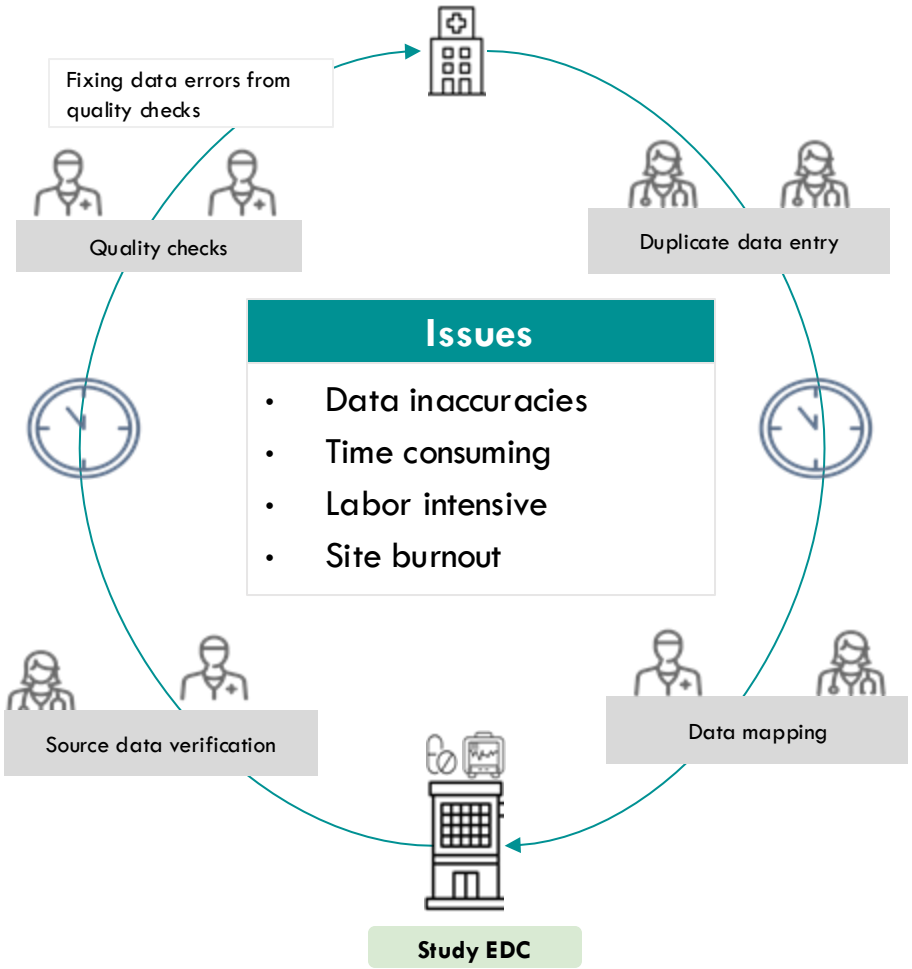
FHIR

AMIA 2024

The opportunity: Breaking free from the constraints of EDC forms

Current state of data for clinical studies

100% Manual Entry

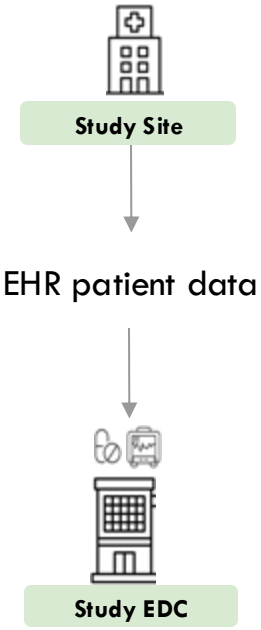


Issues

- Data inaccuracies
- Time consuming
- Labor intensive
- Site burnout

Potential of EHR data connectivity

70% Automated & 30% Manual Entry



Potential Benefits

- Labor savings
- Improve study economics
- Reduce/eliminate source data verification (SDV)
- Broader data available
- Improve site engagement

eSourcing for Medical device registry

Case study

The Long-Term Outcome and Quality Indicator Impella Registry (LOQI)

Study Design

Prospective, real-world data (RWD), all-comers registry of patients supported by any Abiomed Impella device for any purpose

Ease of data entry

Designed to decrease the data entry burden on collaborating sites
CRFs contain ~400 fields maximum (only if every field is filled out)

Objectives

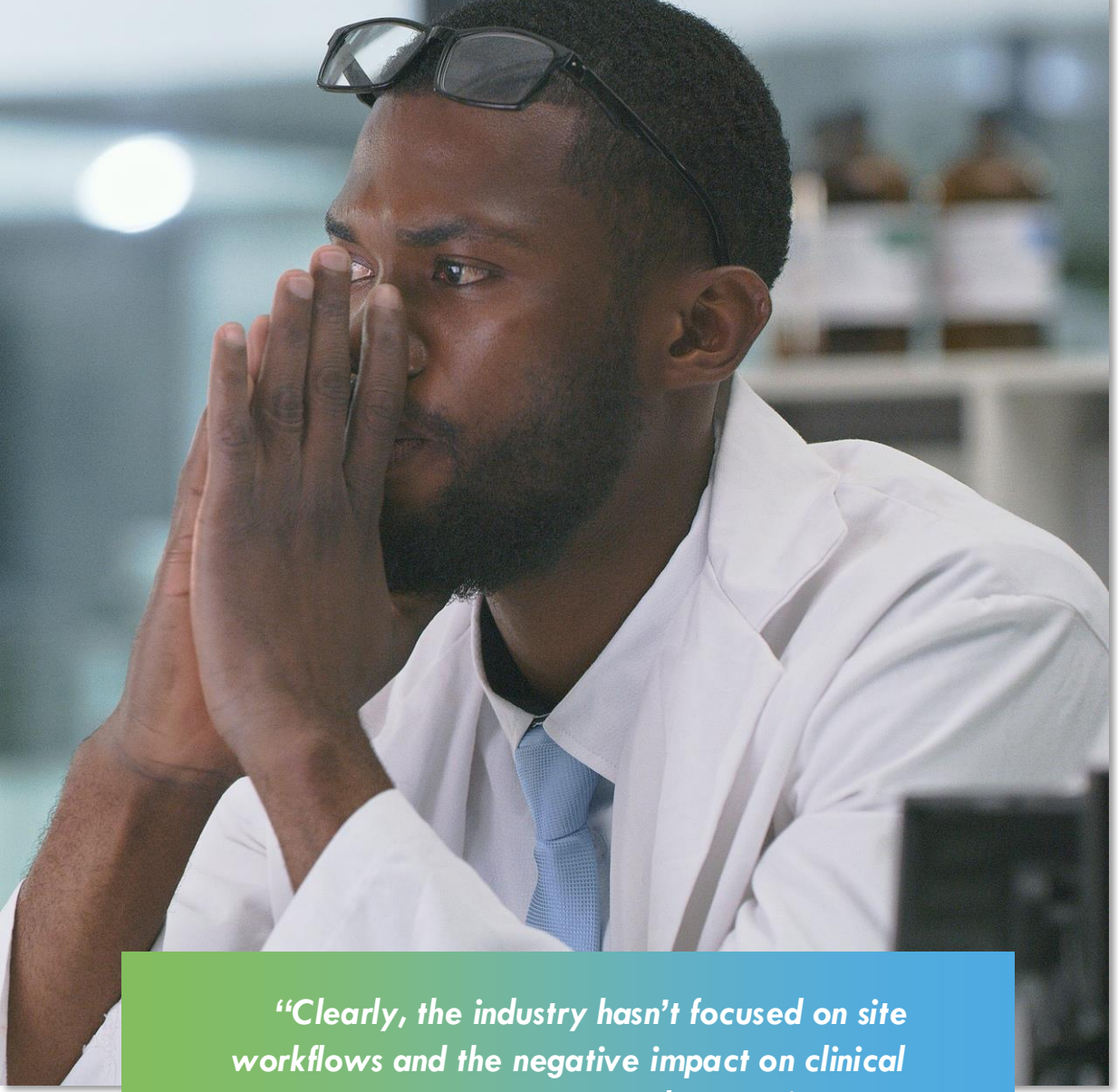
-Allow real-world surveillance of safety events
-Identification of best practices
-Support hypothesis-generating research
-Support regulatory filings

Data collection

Entered from index hospitalization through 1-year post-device implant. Includes routine medical care data, specific safety events, device practices, standard of care.

Administration

Central IRB-approved (WCG IRB) study conducted under a waiver of informed consent



"Clearly, the industry hasn't focused on site workflows and the negative impact on clinical research operations …"
- Data Engineering/Analytics Manager

Lack of staff and burnout is a core problem at health systems

Manual entry into EDC forms is time-consuming, and subject to human error

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

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

x Staff is busy with higher value tasks

x Confidence in the right values/endpoints

x Site inability to support study

Source data verification (SDV) is often necessary for manual data transfer into EDC forms and adds up

Cardiovascular 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-December)

Site X was queried >1,400 times to resolve discrepancies (Source Data verification/SDV) of discrete data fields entered into the 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 FTE workdays)

The CLEHR solution

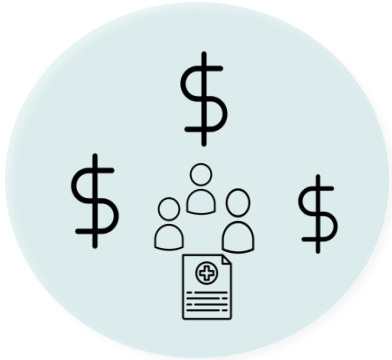
Roadblocks for sites providing EHR data for clinical research

Costs of Application Programming Interfaces (APIs)

- No toll-free access to the Electronic Medical Record (EMR)
- Start up costs from the EMR API licensing can outweigh single study cost-saving benefits

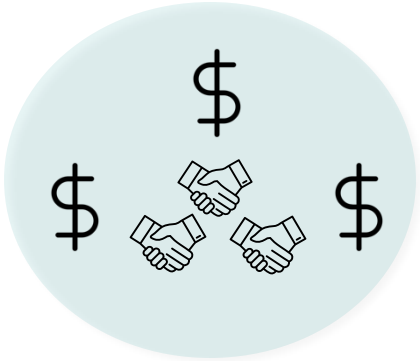
Set-up complexity

- Implementation of mapping tools are often resource-heavy IT projects
- IT projects are costly and typically run 6+ months to implement (each time)
- IT teams are unavailable due to other priorities



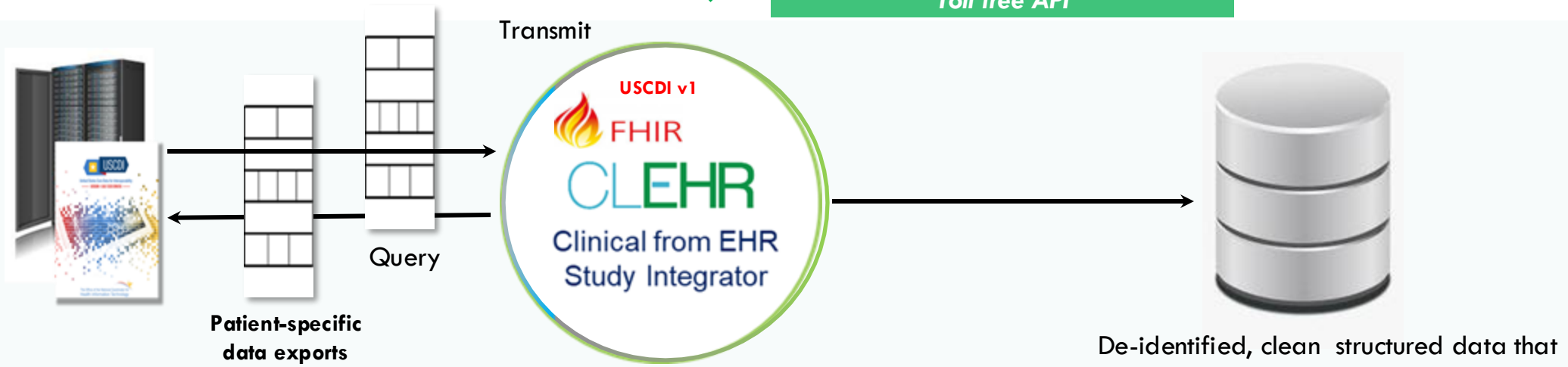
Too many vendors

- Each study requires a new vendor start up process
- Each vendor must be vetted (audit security protocols, cloud)
- Each vendor requires a new integration project, maintenance plan

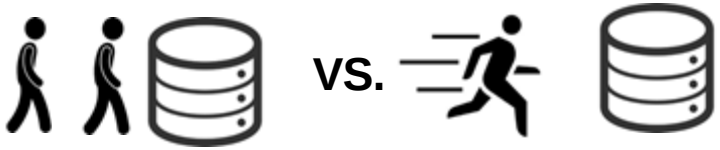


FHIR-enabled eSourcing drives efficiency, ensures data quality and accuracy

USCDI - no EMR API access cost:
Toll free API



Reduces delays in entering of data

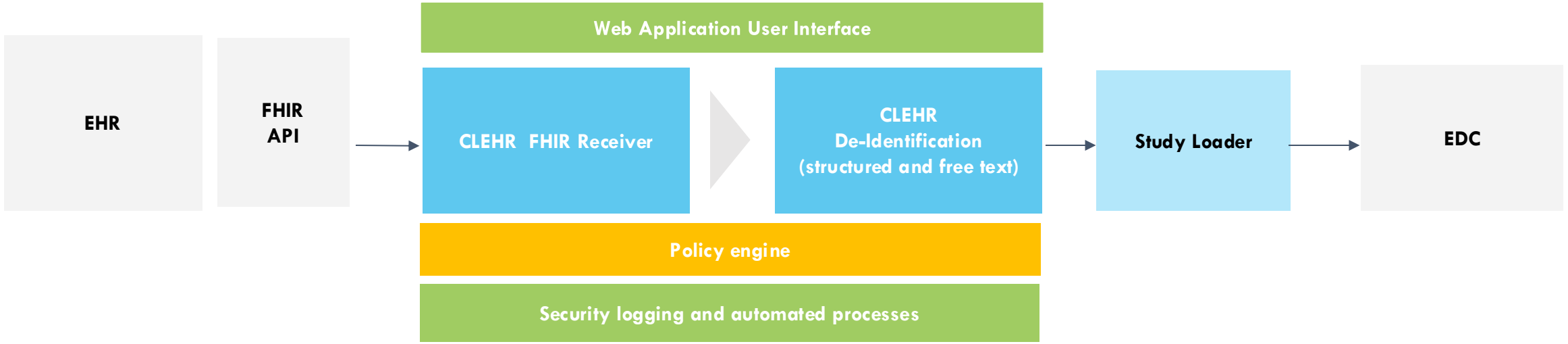


Data integrity eliminates SDV

Limited to no need for Source Data Verification

CLEHR architecture opens standard, secure and designed to scale

CLEHR



FHIR

USCDI v1

USCDI V1 and FHIR

The tool extracts data from the EHR system using open standard FHIR. . 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

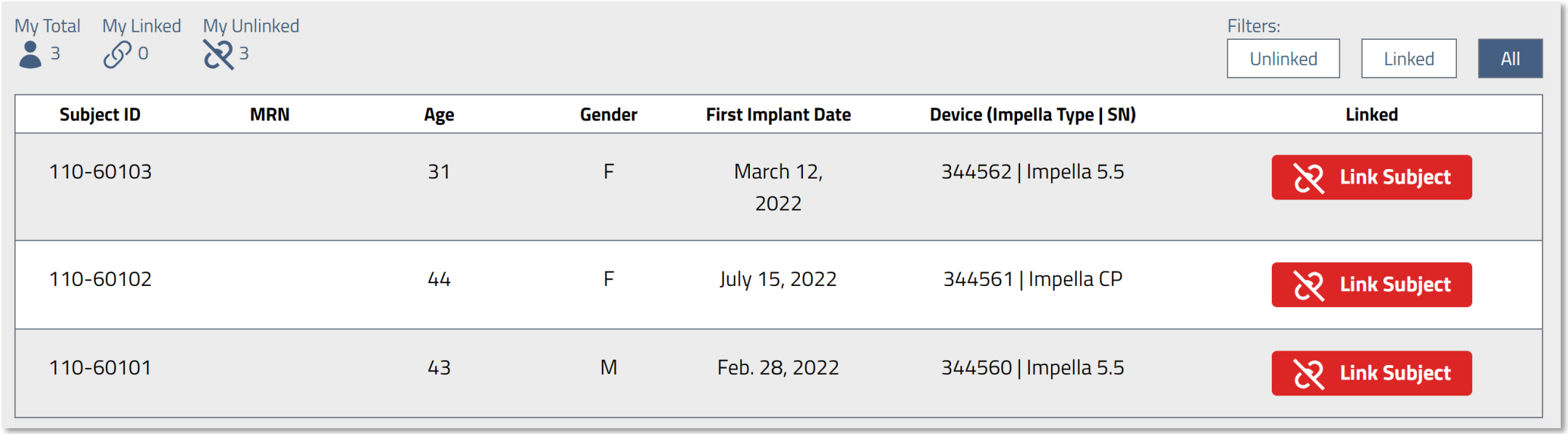
Security and Compliance

Hosted on a secure cloud environment

Implemented controls for HIPAA and HITRUST using ClearData compliance management software

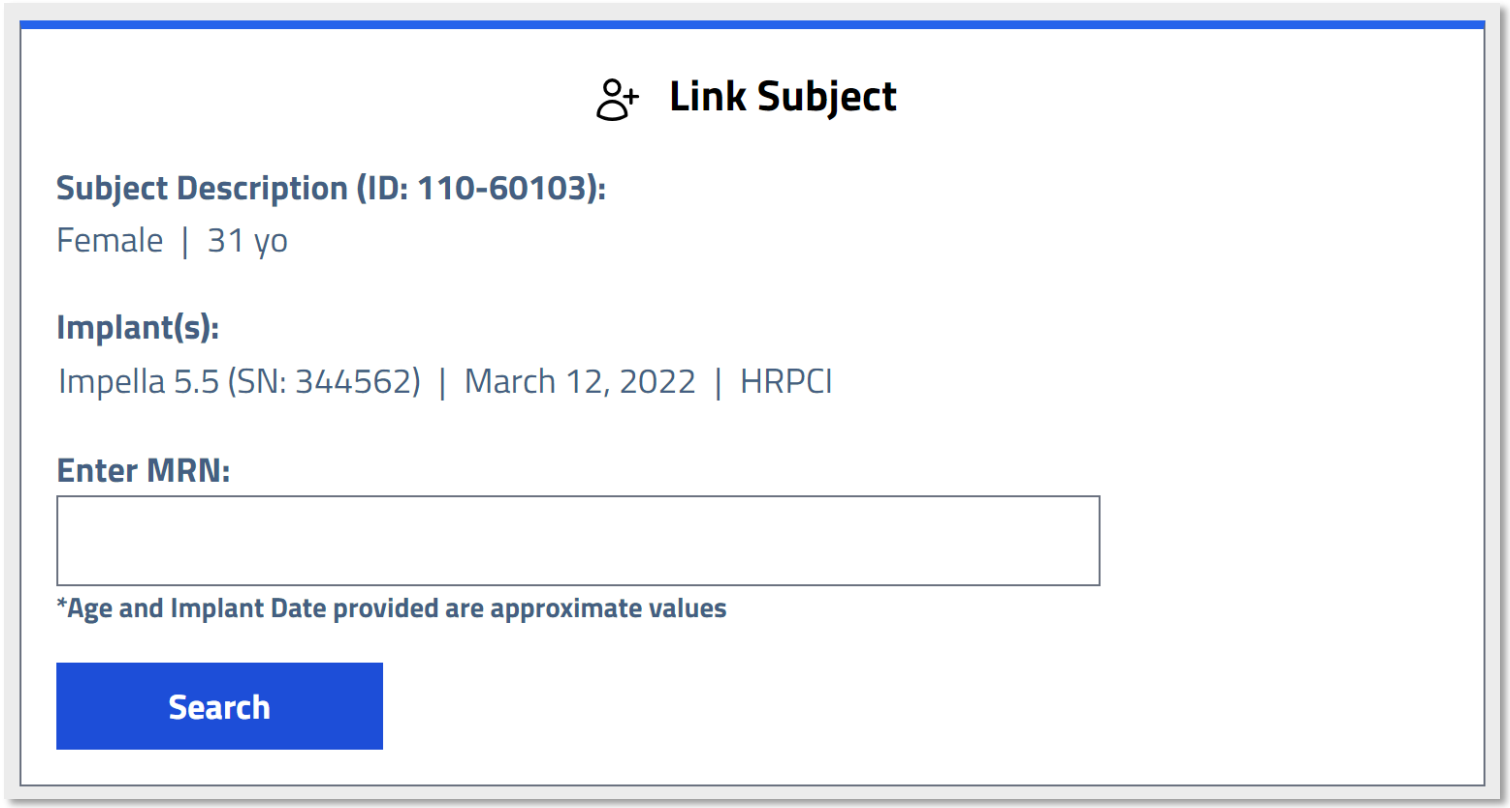
Demo: subject linking

Subject IDs are pre-populated
Updates sent weekly by CLEHR
Review subject demographic and device information in EMR
When subject is confirmed, click the “Link Subject” icon



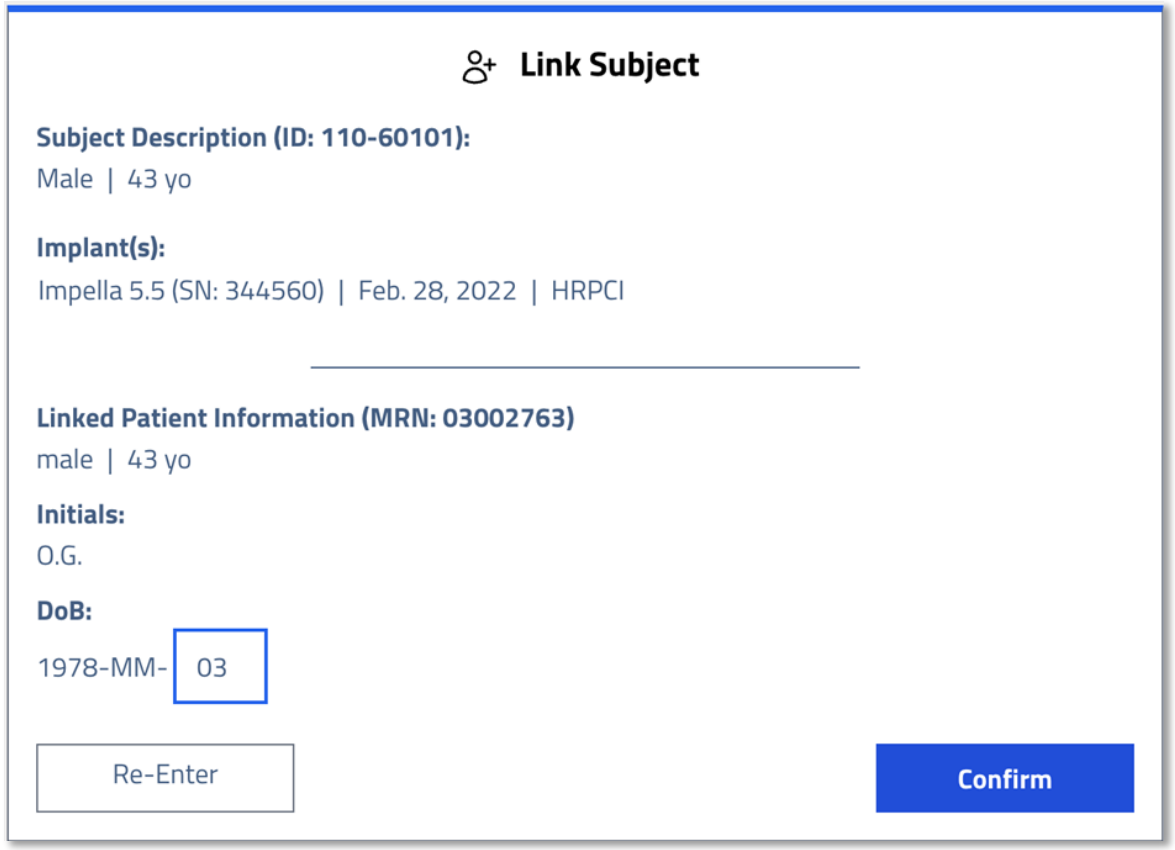
Demo: subject linking

Link subject by entering the MRN, then click “Search”



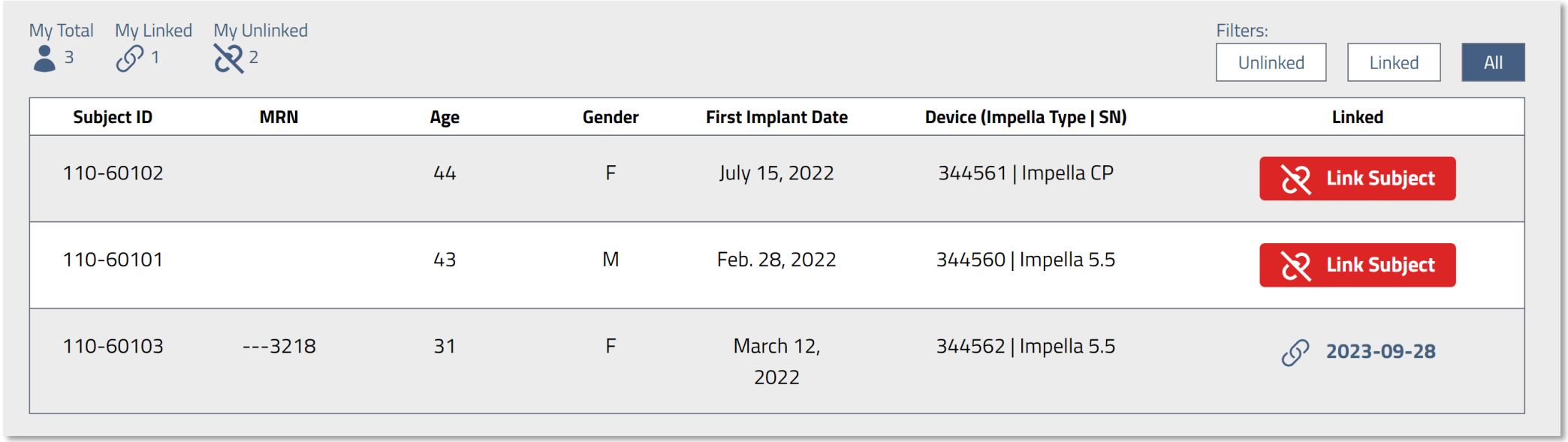
Demo: subject linking

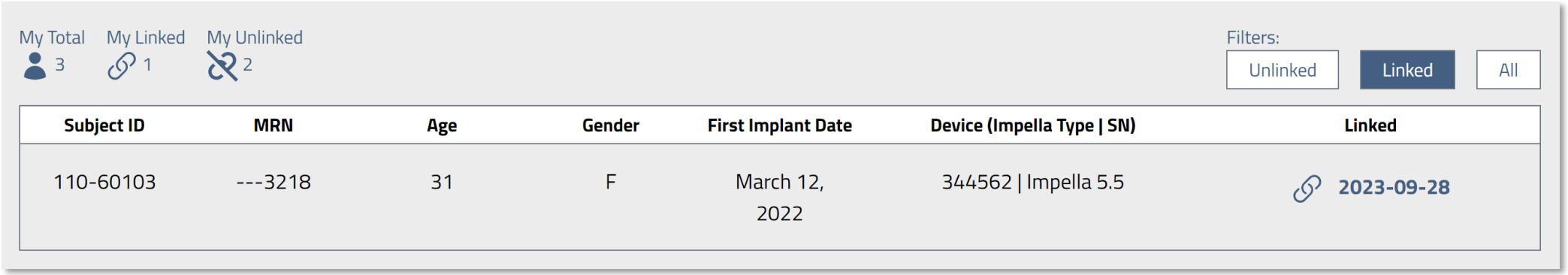
Complete date of birth, enter day (DD), click “Confirm”



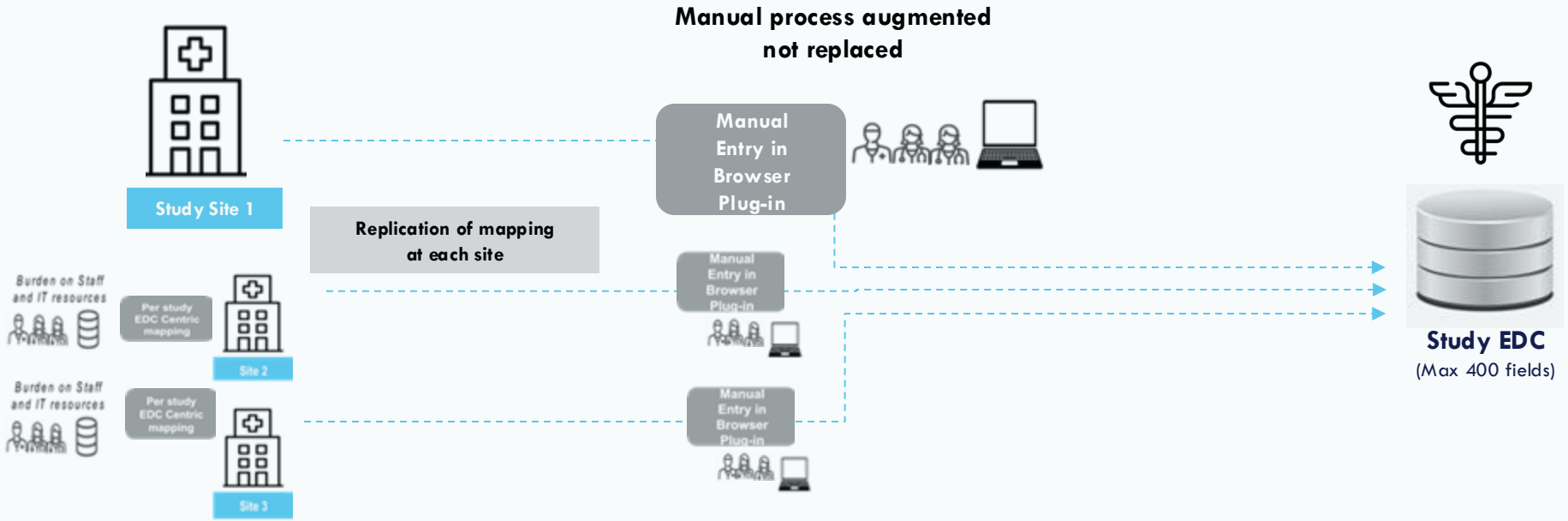
Demo: subject linking complete

Once linked, the “Link Subject” icon is replaced with date of subject linking



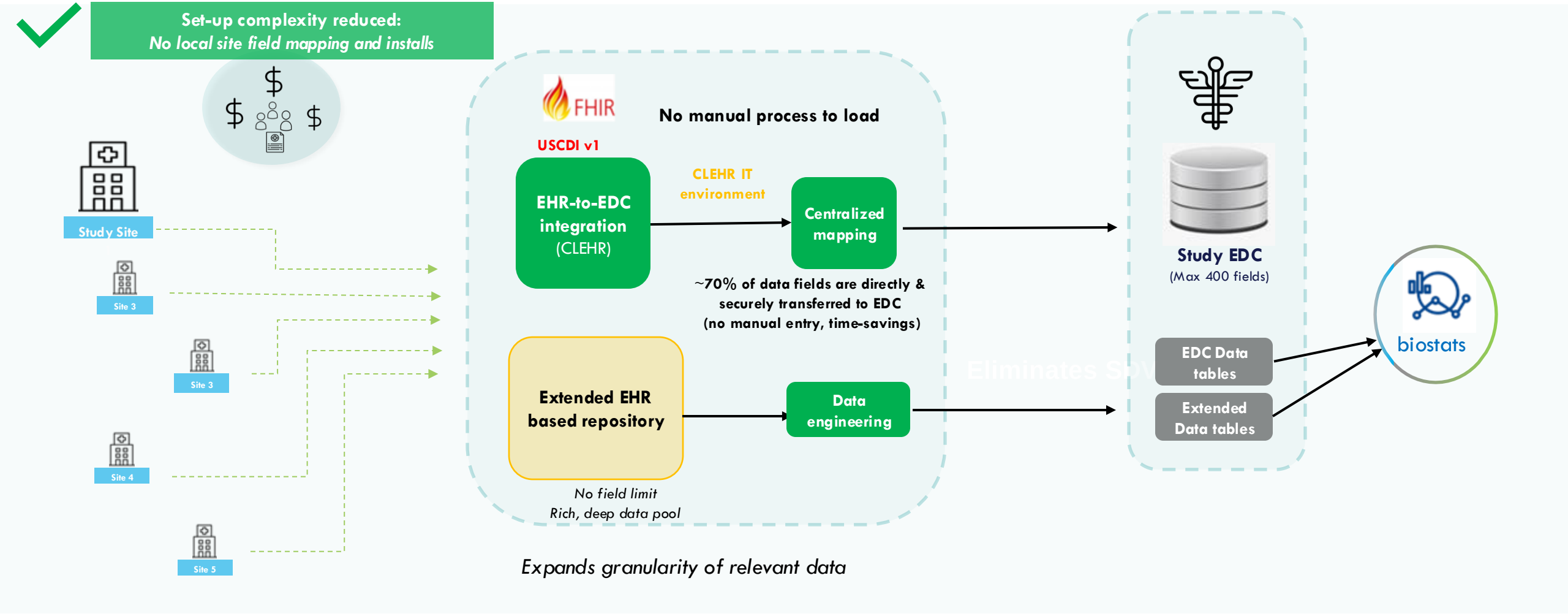


Why eSourcing vs. mapping? Mapping tools require repeat work and entry at each site plus long implementation times



X Clinical Research Coordinators still face labor-intense work
X Limited to form fields - does not expand or diversify available data
X Poor support for valuable, correlated-in-time values such as labs

FHIR-enabled eSourcing yields richer data beyond the constraints of the EDC



Where eSourcing saves time: POV from a Clinical Research Coordinator at a Health System

Case entry normally takes about two hours+ depending on the patient LOS. The CLEHR interface can save 45 minutes or more of repetitive entry

Medication history is important but it has always been time-consuming to review multiple lists, histories and physicals … Automation can reduce the searching. We would like NLP of the notes for this.

Labs are simple to sort but time-consuming to capture. Integration eliminates this activity for me.

Reading the cath report helps with capture of start and end times. We need to manually review cath reports line by line but we would like your team to process the report to eliminate this step.

We still need EDC forms for the more complex judgement situations such as reviewing an adverse event with the PI prior to submission. It's good to have more time to get it right

A study is planned in 2025 for time savings

FHIR-enabled eSourced data supports advanced research analysis

Rich, granular relevant data provides a more accurate clinical picture of the patient

eSourced vs, manually transcribed research data

- 291 BP measures vs 2 measure time points with manual EDC transfer
- 360 tracked patient encounters vs. manual 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

View of a single patient's data available thought eSourcing

Implementation

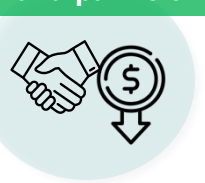
“CLEHR inside” honest broker approach reduces complexity integrating CROs and other sponsor stakeholders into the network

Graticule implements only the essential functions to activate sites efficiently

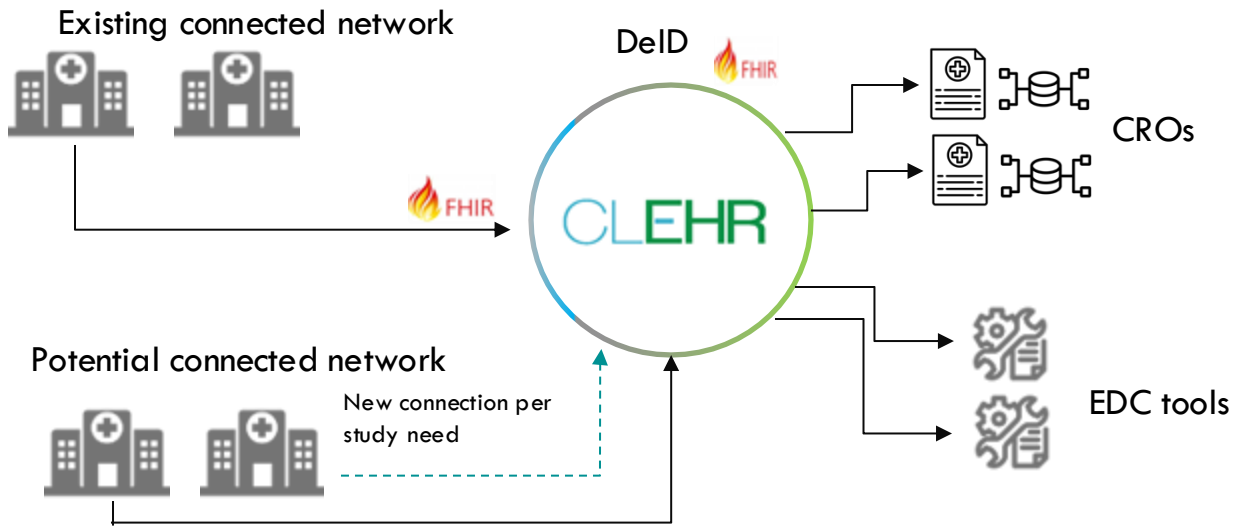
By fostering technical integrations with CROs or EDC interfaces with mapping utilities, CLEHR reduces the burden on health systems through a multi use connection

This strategy simplifies the process reduces the need for numerous integrations, interfaces and vendors.

Solution: 1 connection to enable many studies and partnerships



Working with Graticule to connect to CLEHR connects the health system to a broader sponsor clinical research ecosystem



CLEHR essential functions, solving for the minimum set of issues

The site always has control over which patients are included in the study by controlling the MRNs

CLEHR manages identity mappings into downstream systems such as the mapping between an MRN and a research ID in an EDC with a process to do so that works efficiently for the site

CLEHR de identifies records including free text based on the specifications of the protocol it is supporting

Graticule signs a BAA or equivalent with the site to handle the fact that Graticule is processing identified patient data for the purpose of running a study

CLEHR only conveys the data agreed upon in the protocol and limits it either by not requesting it or by reducing the data set prior to transmission to the downstream system

CLEHR provides transparency back to the site and sponsor systems of what occurs

The health system can turn off use of CLEHR at any time by shutting off access to the FHIR API

Low activation effort to minimal effort for the IT department

Single, one-time set up and onboarding process for Health Systems

Once implemented, the system is ready to support *any future study*

Contracting, BAA & Other Pre requisites ✓ → Implementation, testing, validation and GO Live ✓

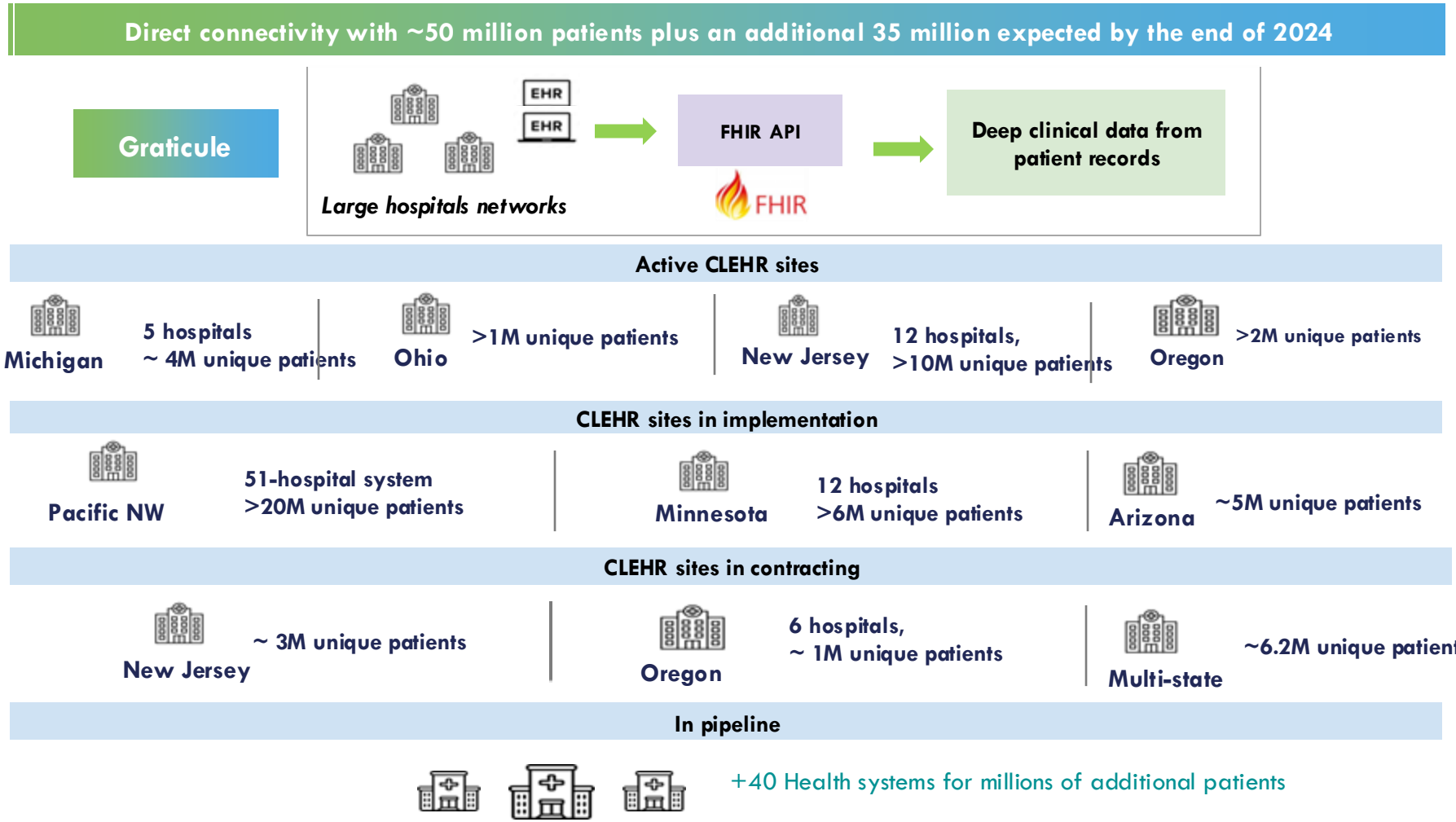
3-9 months | 1-2 weeks

CLEHR is available in the Epic Showroom

Following the 1st implementation, CLEHR (USCDI v1) was validated for the Epic Showroom marketplace in December 2023

The network

CLEHR network: interface to 50-80 million+ patient records and growing



Impact on clinical informatics: where data science and clinical knowledge can be applied in new ways

- *Access data not available in the research warehouse or with lower latency*
- *Generate disease specific pipelines to run NLP or LLMs to extract features from FHIR and plug into CLEHR APIs to scale use*
- *Establish collaborations flexibly with peer health systems towin grants and answer hard research questions*
- *I can request access to EMR data from more diverse patient populations for observational studies*

Summary

The power of a simple scalable connection
CLEHR USCDI-based honest broker network lowers EDC burden and boosts research opportunities

Toll free access to the EHR with the right controls in place

1 connection, 1 vendor to work with many partners (CRO, EDC, peers) to scale sponsored research

Low lift, 1-time activation lowers burden on CRCs and meets ongoing sponsor selection criteria

Rich, granular EMR data enhances clinical insight and enables clinical informatics and data scientists

Solving key problems for sites

Costs of Application Programming Interfaces (APIs)

Mapping complexity

Too many vendors

THANK YOU