

CBER BEST IM Exchange Pilot

Biologics Effectiveness and Safety Innovative Methods

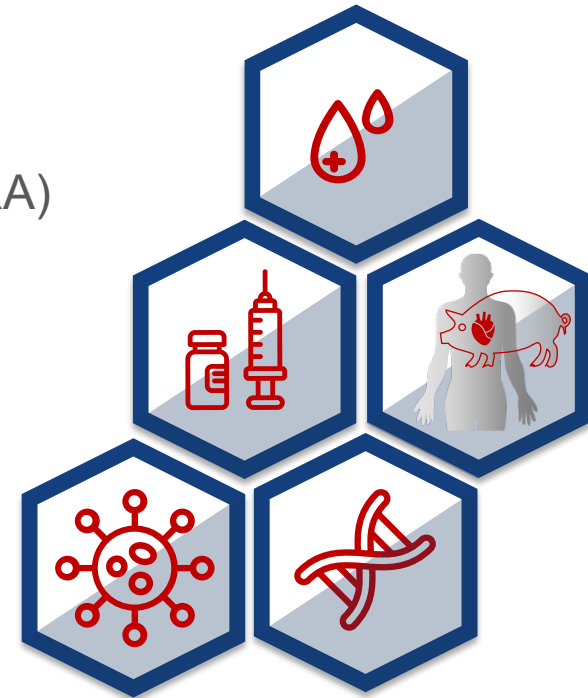
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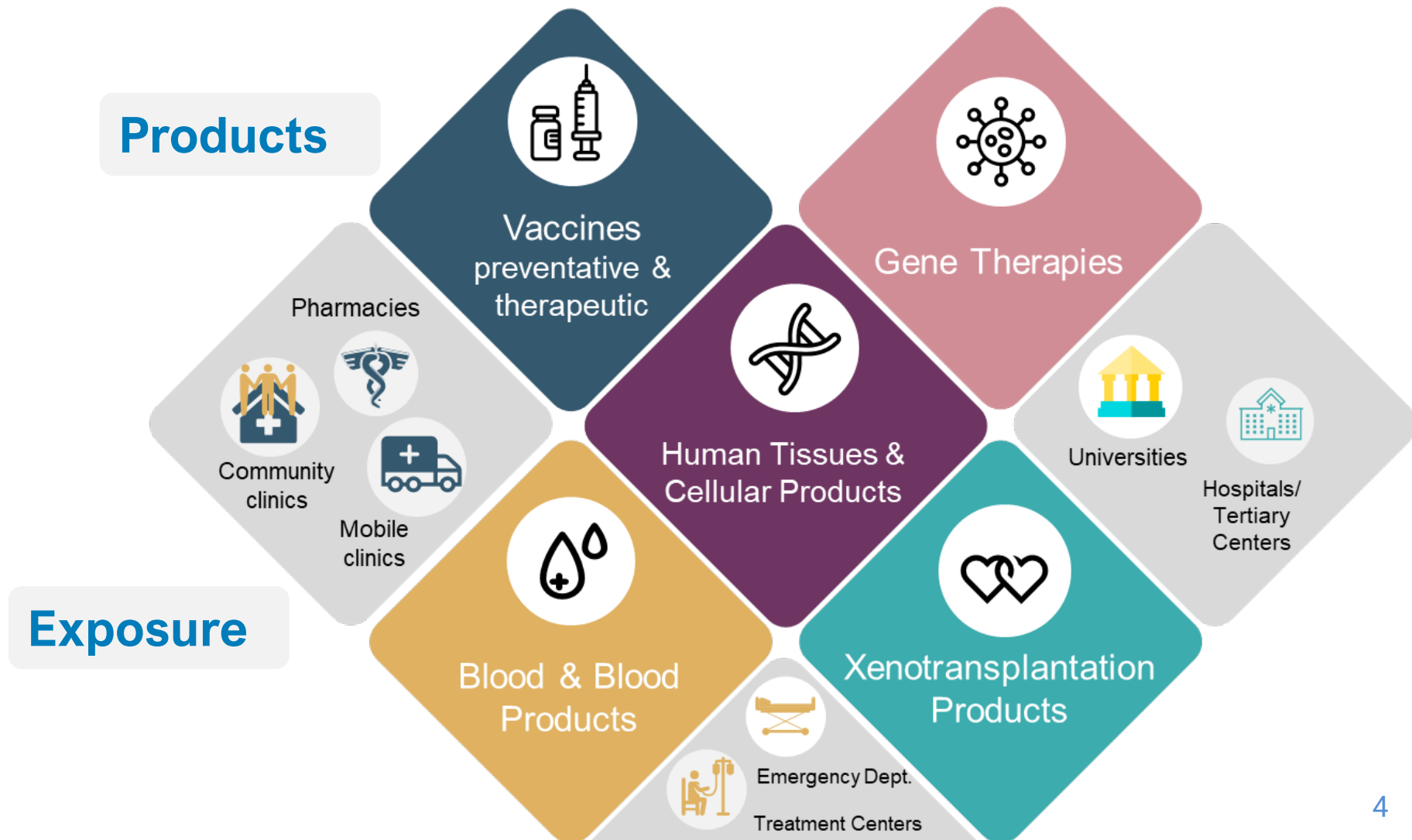


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- **Background**
- **Exchange Pilot**
- **Results**
- **Conclusion and Summary**

Background: *CBER Portfolio*

CBER-Regulated Products



Background: *Challenges*

Clinical **exposure** and potential **outcome**

Current

Manual Detection



Individual flagging of potential AEs

Under-recognition of outcomes

Manual Validation



Time-intensive to review dispersed data

Potential AEs **not always communicated**

Case definitions separate

Manual Reporting



Data re-entry to report externally

Lack of granularity in report evidence

vs.

Future

Automated Detection



Batch detection, more focus on patient care

AI algorithm scores potential cases

Semi-Automated Validation



Evidence integration reduces burden

Flagged and prioritized cases sent for review

Case definition integrated

Semi-Automated Reporting



Auto-population of granular ICSR evidence

Generation of evidence-based ICSR narrative

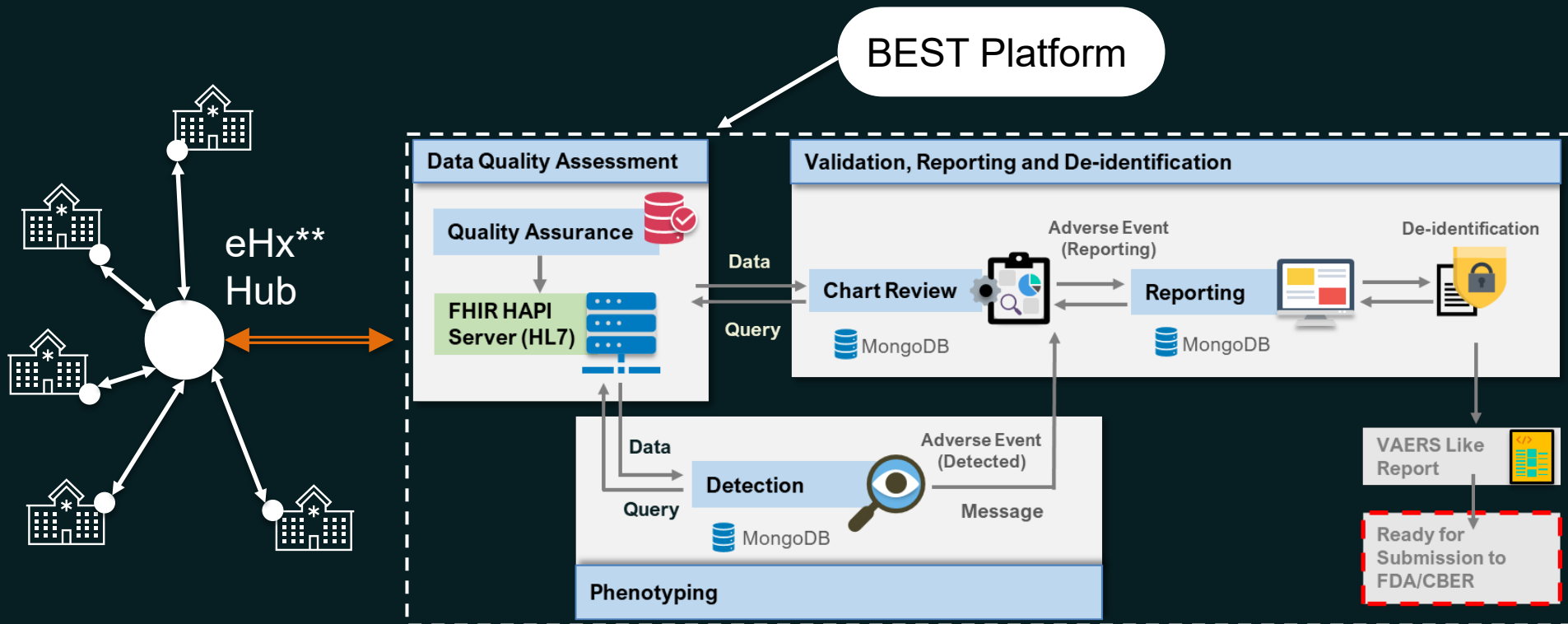
Existing Manual Process Creates Burden

BEST Platform demonstrates use of **innovative methods** to **reduce burden**, while **increasing quantity and quality** of AE reports

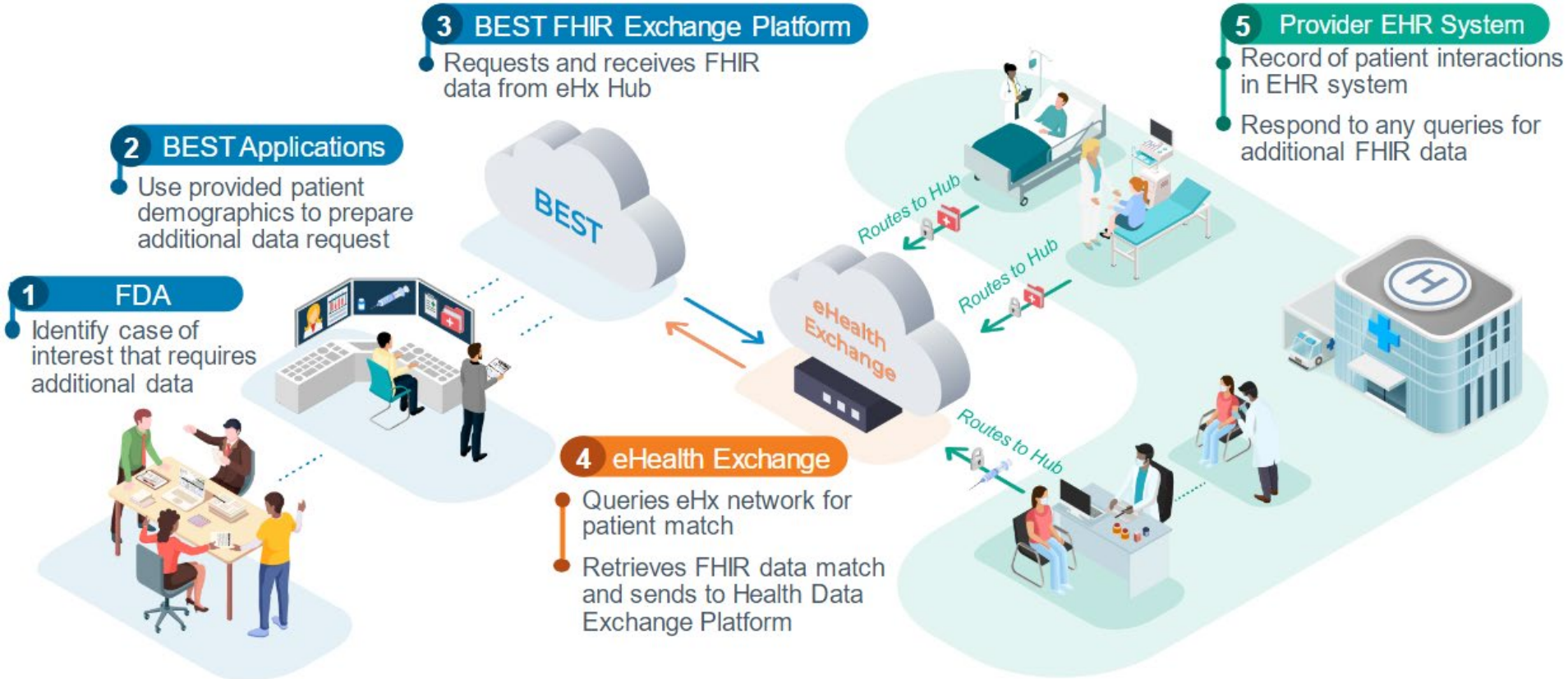
ICSR, individual case safety report

BEST Pilot Platform

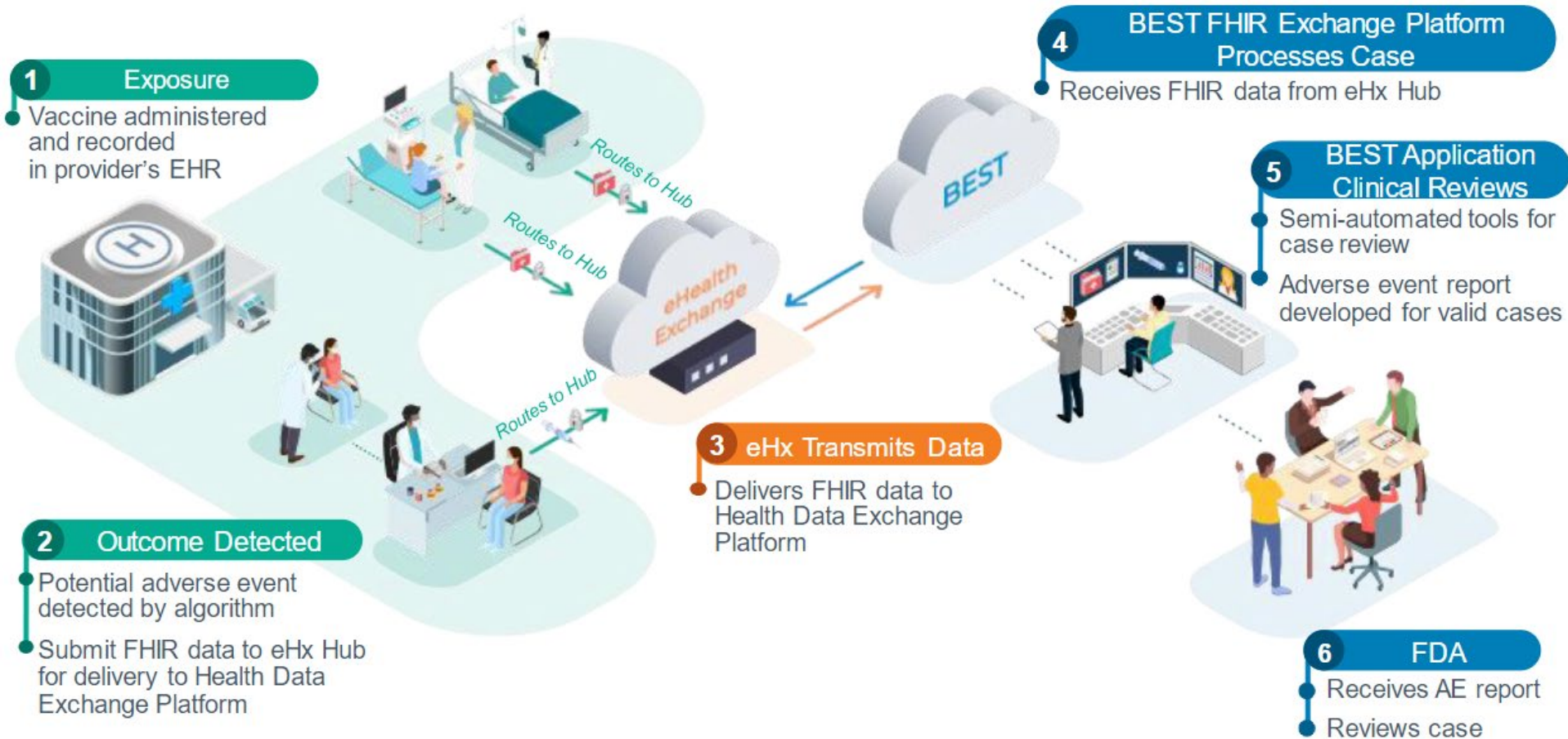
BEST* Innovative Methods (IM) Initiative developed a Pilot Platform to address current challenges through AI and automation.



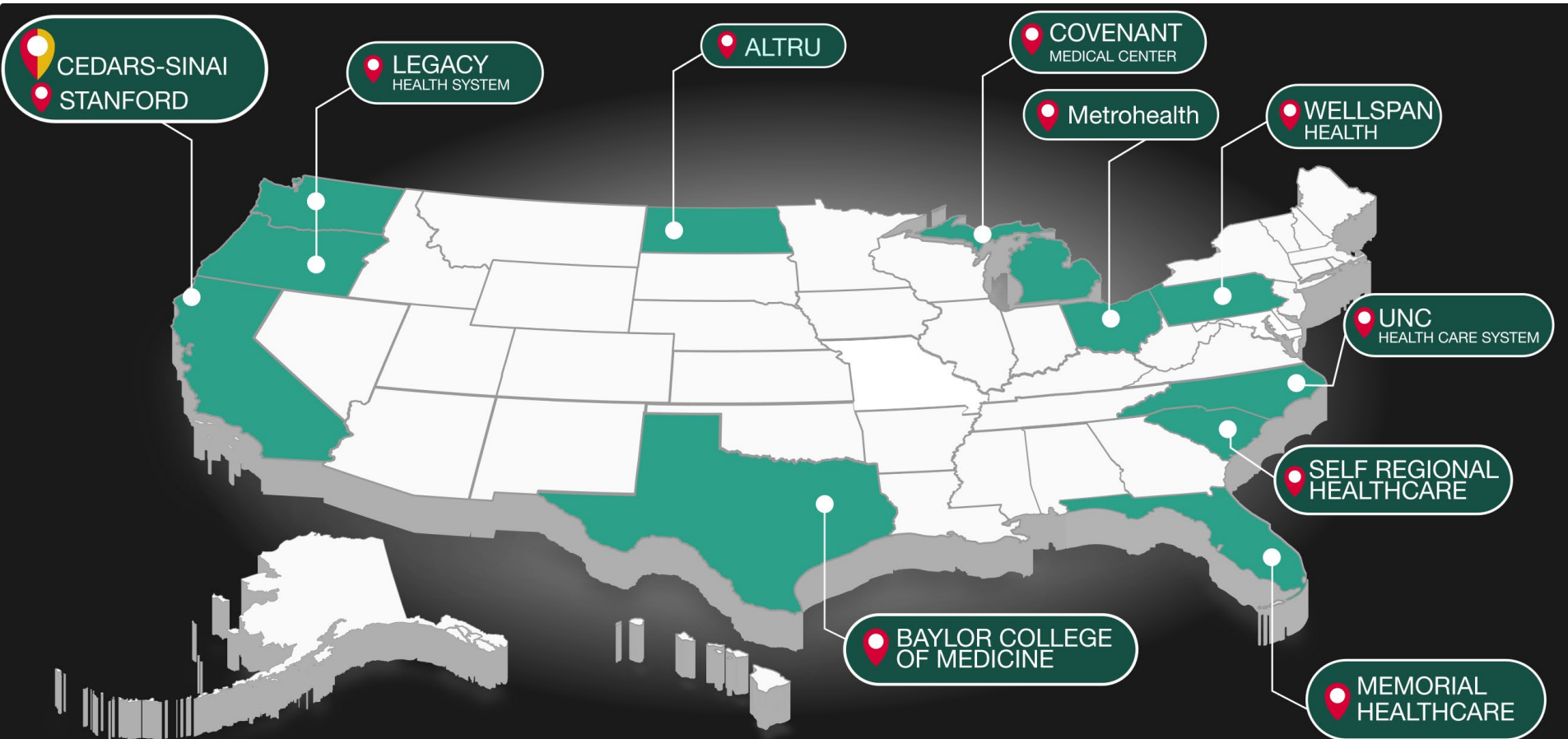
Validation (Pull) Use Case



Detection (Push) Use Case

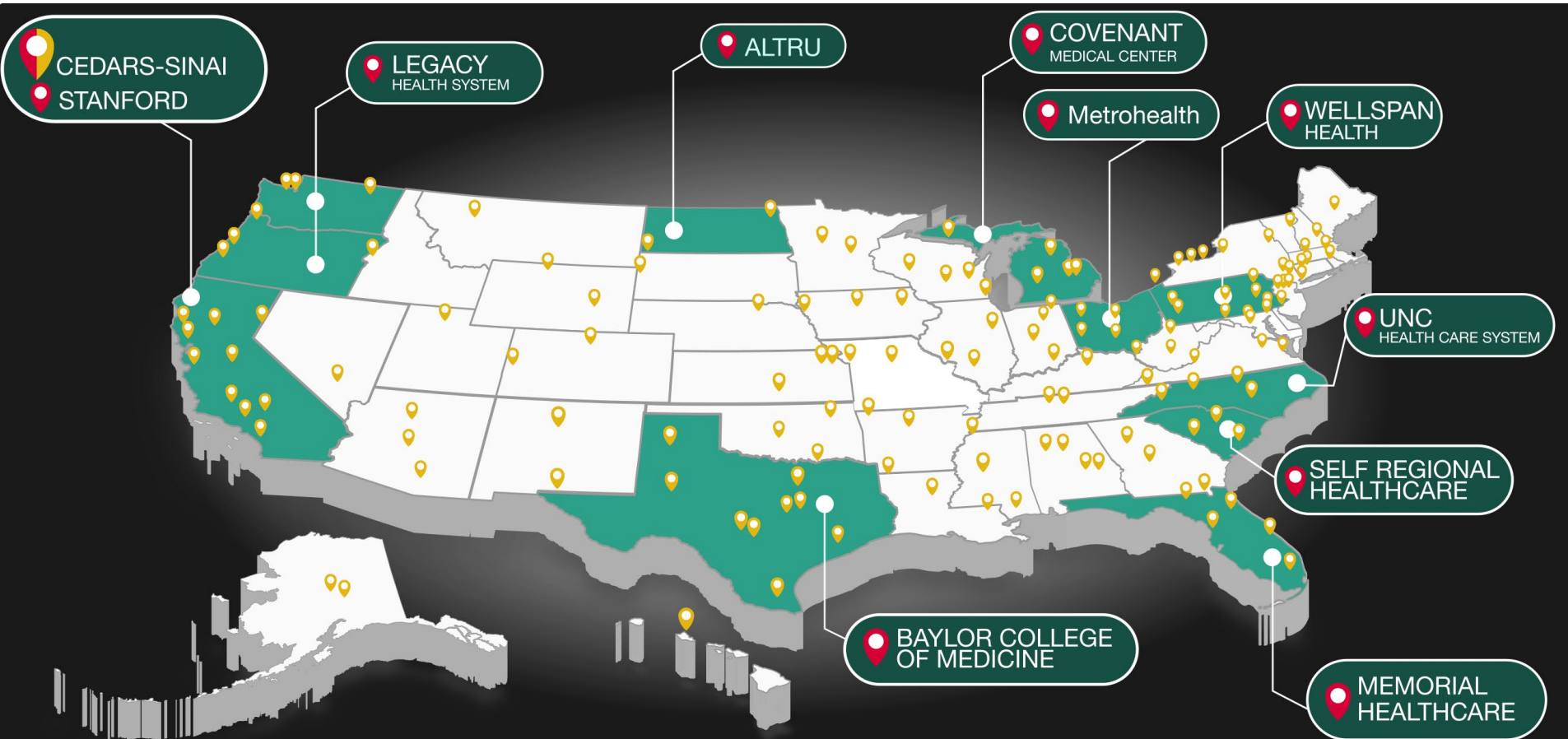


Pilot Participants



 Pull Use Case  Push Use Case  Push/Pull Use Case

Pilot Participants



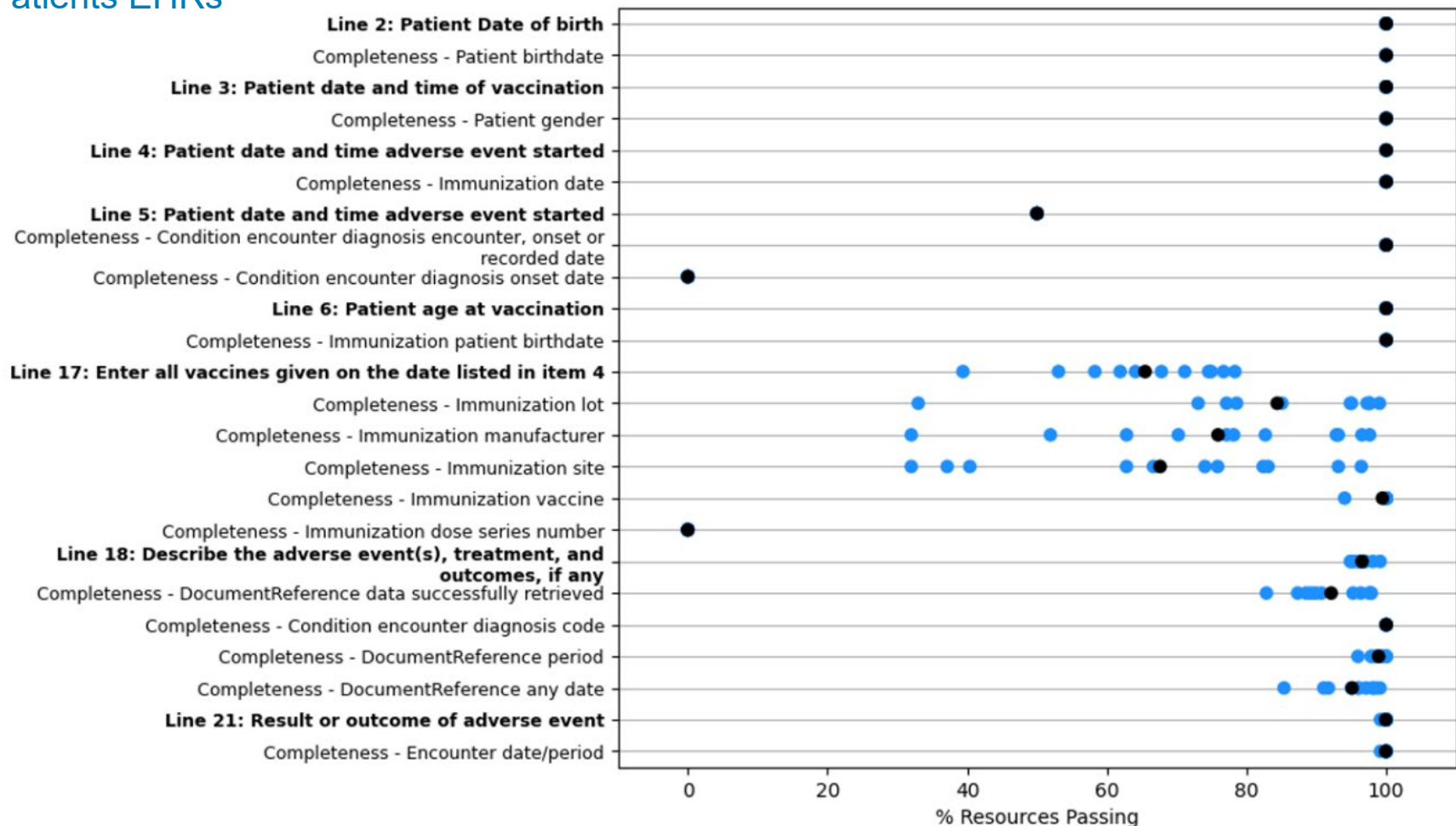
 Pull Use Case  Push Use Case  Push/Pull Use Case

Pilot Results

- 271 post-vaccination AE were queried
- Across 11 different health provider data partners (Epic EHRs)



* Patients EHRs



- For CBER's use case, **the overall data quality meets general requirements**, as partner's EHR HL7® FHIR® APIs are showing high adherence to USCDI data set
- **Variability** - even with same EHR vendor - in security authorization settings, required trail and error with individual partners
 - The team worked with EHR vendors to create a new policy that standardizes this process across partners to reduce the connection set-up time
- Important gaps include, **lack of inclusion in USCDI data set**, and **varying levels of completeness** across partners
- The BEST team continues to enhance the Platform infrastructure to enhance CBER's passive and active post-market surveillance capabilities:
 - improve our querying capabilities
 - efficiently federate AE detection logic
 - conduct evaluation and validation studies

Acknowledgement

FDA CBER

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IBM

Lance Jones, Matthew Deady, Brian Goodman, Haley Huang, Deepa Youssef, Kathryn Matto

eHx

Jay Nakashima, Eric Heflin, Mike Y and Mike M

Pilot Participant

- **CEDARS-SINAI HEALTH SYSTEM** (early adopters)
- **VETERANS HEALTH ADMINISTRATION (VHA)** (early adopters)
- WELLSPAN HEALTH
- UNC HEALTH CARE SYSTEM
- SOUTH BROWARD HOSPITAL DISTRICT DBA MEMORIAL HEALTHCARE SYSTEM
- STANFORD HEALTH CARE
- THE METROHEALTH SYSTEM
- ALTRU HEALTH SYSTEM
- BAYLOR COLLEGE OF MEDICINE
- COVENANT MEDICAL CENTER
- GREENWOOD COUNTY HOSPITAL BOARD DBA SELF REGIONAL HEALTHCARE
- LEGACY HEALTH SYSTEM

- [Vaccine Administrations From Unstructured Data in Medical Records Through Natural Language Processing](#)
- [Detection of allergic transfusion-related adverse events from electronic medical records](#)
- [FDA 2021 Science Forum: CBER BEST: Leveraging AI to Build an Automated Adverse Event Reporting System](#)
- [AI article about BEST C2 in FDA 2021 Science Forum](#) July 2021
- [Balloted BEST FHIR IG](#)
- [BEST FHIR IG on Interoperability Standards Advisory \(ISA\)](#)
- [BEST HL7 Case Study](#)