

# Building UDI Into Longitudinal Data for Surveillance and Research (BUILD)

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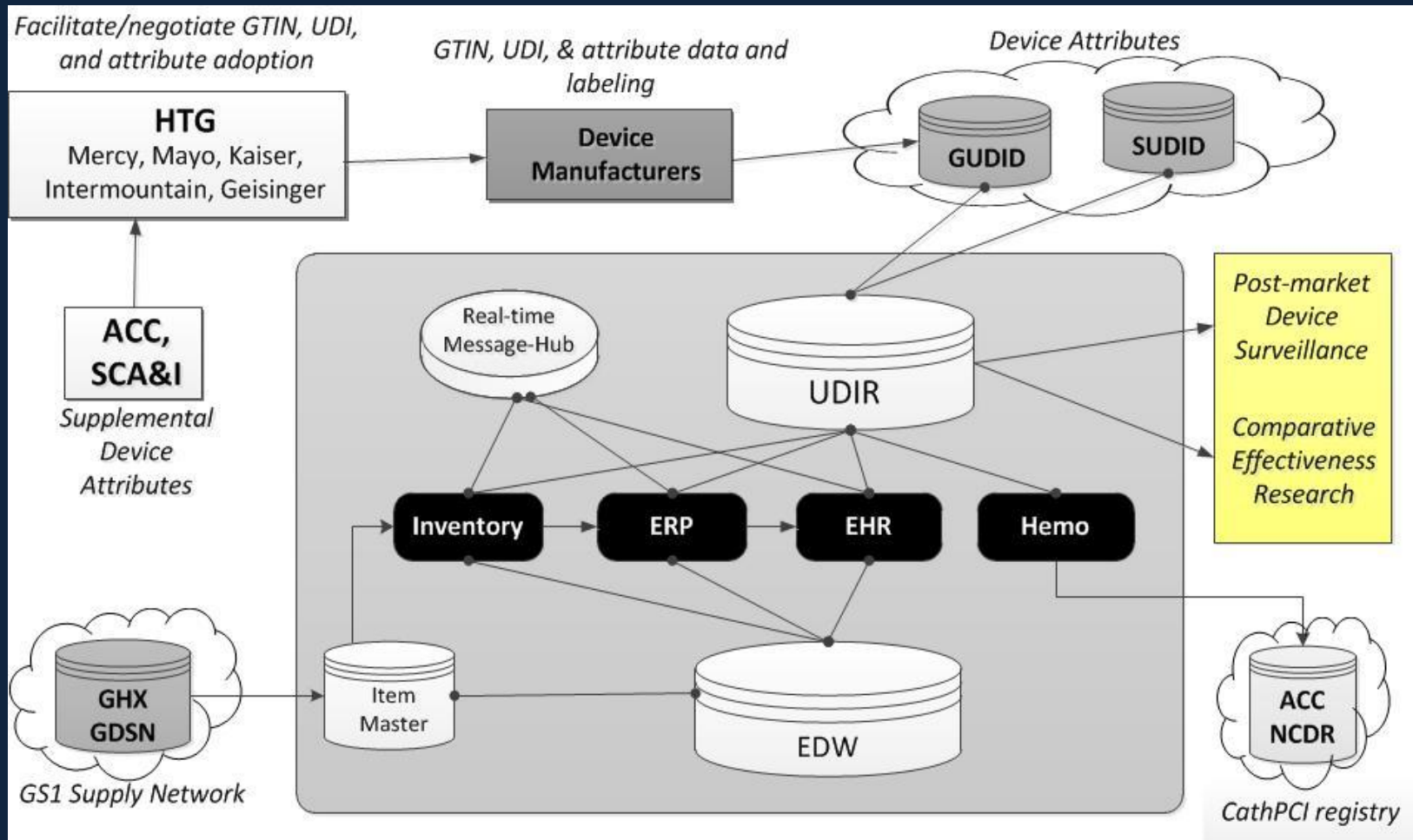
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# Components of BUILD

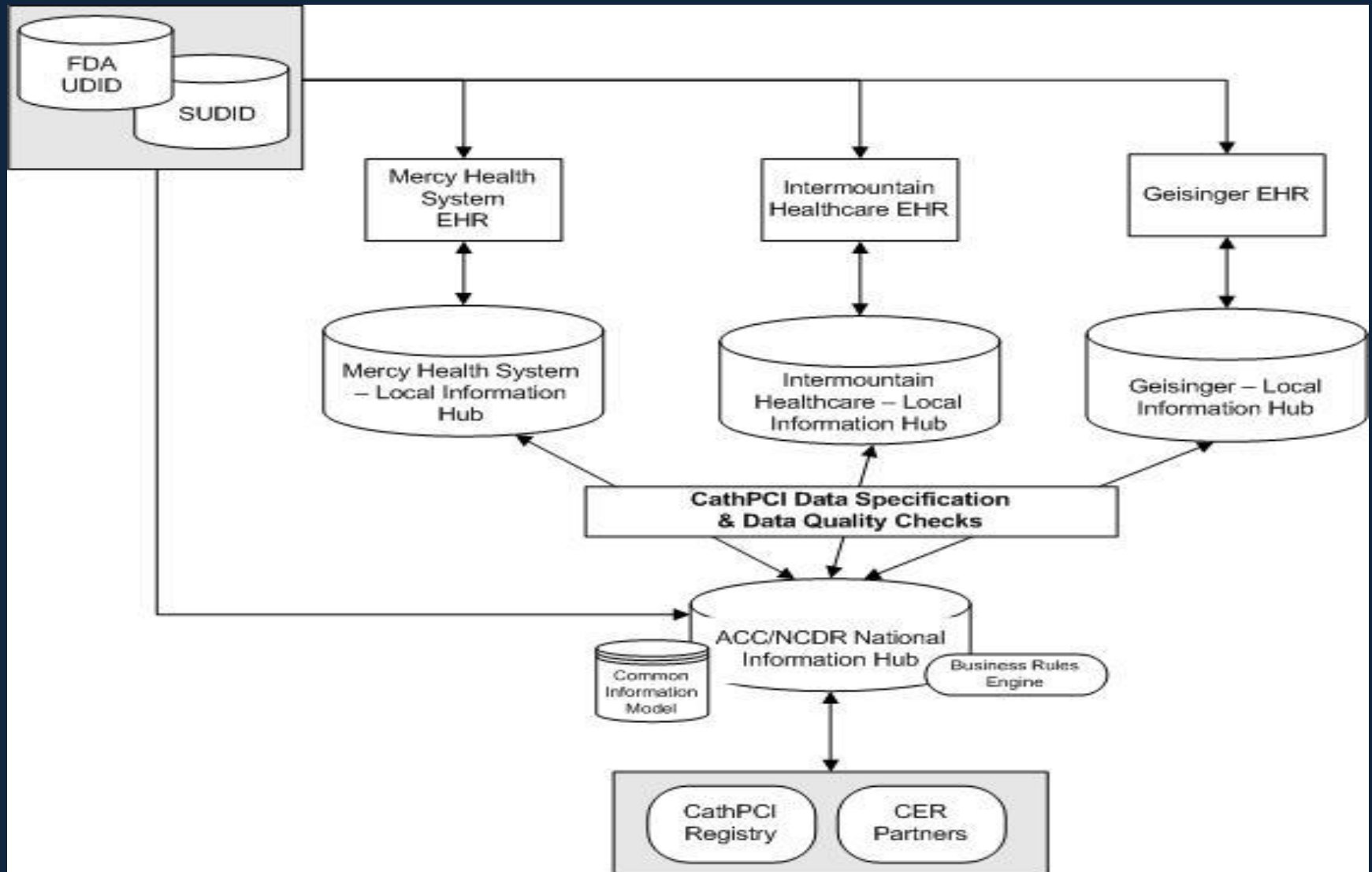
- Extension of UDI Implementation Pilot
- Electrophysiology structured reporting providing UDI for Leads and devices using industry Standards to Electronic Health Records and CVIS systems (EPulse)
- Medical Device Data Capture and Exchange: Leading Practices and Future Directions

# Mercy UDI Demonstration Project

## High Level Architecture



# The BUILD Distributed Data Network



# Electrophysiology Structured Reporting Providing UDI for Leads and Developing Industry Standards to Electronic Health Records and Cardiovascular Imaging Systems (ePulse)

- Incorporate UDI data into structured reporting for cardiac electrophysiology pacemaker and ICD implant/explant reports
- Uses IHE Electrophysiology Report Implant/Explant profile
- UDI transmitted to structured report (cCDA document) for consumption by EHRs

# Medical Device Data Capture and Exchange: Leading Practices and Future Directions

- Build a consortium of hospital organization, manufacturer and other stakeholder leaders in UDI implementation and use.
- Assess and document leading practices for capture and exchange of UDI or UDI prototype for cardiac and orthopedic implantable devices.
- Engage IT experts to create new technologic solutions.

# Current Status of BUILD

- Received an award under the FDA's U01FD005476 funding opportunity
- Next step is a kick-off discussion with FDA
- Finalize Statement of Work
- Anticipate completion of initiative in 3 years