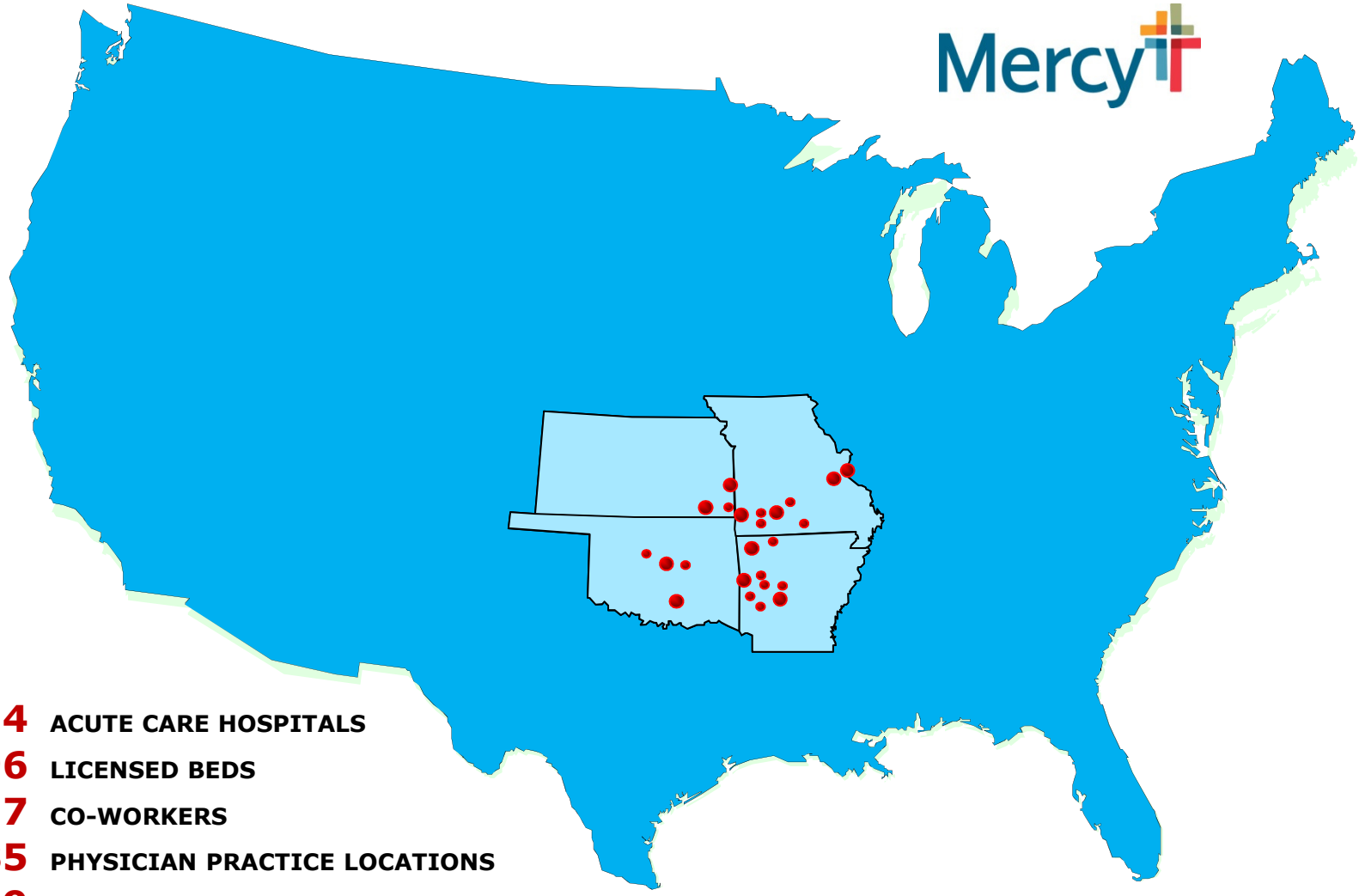
FDA UDI Demonstration

Joseph P. Drozda, Jr., M.D., F.A.C.C.
Mercy Health



34 ACUTE CARE HOSPITALS

4,396 LICENSED BEDS

36,917 CO-WORKERS

185 PHYSICIAN PRACTICE LOCATIONS

4,659 MEDICAL STAFF MEMBERS

1,235 INTEGRATED PHYSICIANS

$4.05 OPERATING REVENUE (Billions USD)

Why Mercy IT ?

The groundwork has been laid by Mercy IT:

The Epic EHR

- 8 years in the making
- All of our hospitals
- All of our integrated physician practices

Why MercyIT ?

The groundwork has been laid by ROi:

The "Perfect Order"

- Fully automated purchase from order to payment

- Enablers
  - Adoption of GS1 standards
    - Global Trade Item Numbers, GTINs
    - Global Location Numbers, GLNs

  - Integration with software (Lawson, OmniceII and TECSYS)

  - Partnership with Becton, Dickenson and Company

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The Mercy UDI Journey

- **Next Steps**
  - Integration of UDI into EHR
  - Creation of data sets containing clinical & device information
  - Linkage to other health systems & national registries (Distributed Data Network)

Why Mercy ?

Something for everyone:

Supply chain team → Find out what works for Mercy's docs and patients

Clinical Support Team → Make life easier

Physicians → Improve Care

- Knowledge of patient's device
- Communication of warnings and recalls (NDC's)
- Ease of reporting Adverse Events

Why MercyIT ?

- Researchers → Comparative effectiveness and safety research
  - Automated collection of significant variables
  - Ability to link with larger data sets
    - HIEs involving data sets of other providers
    - National registries
  - Enhanced safety monitoring

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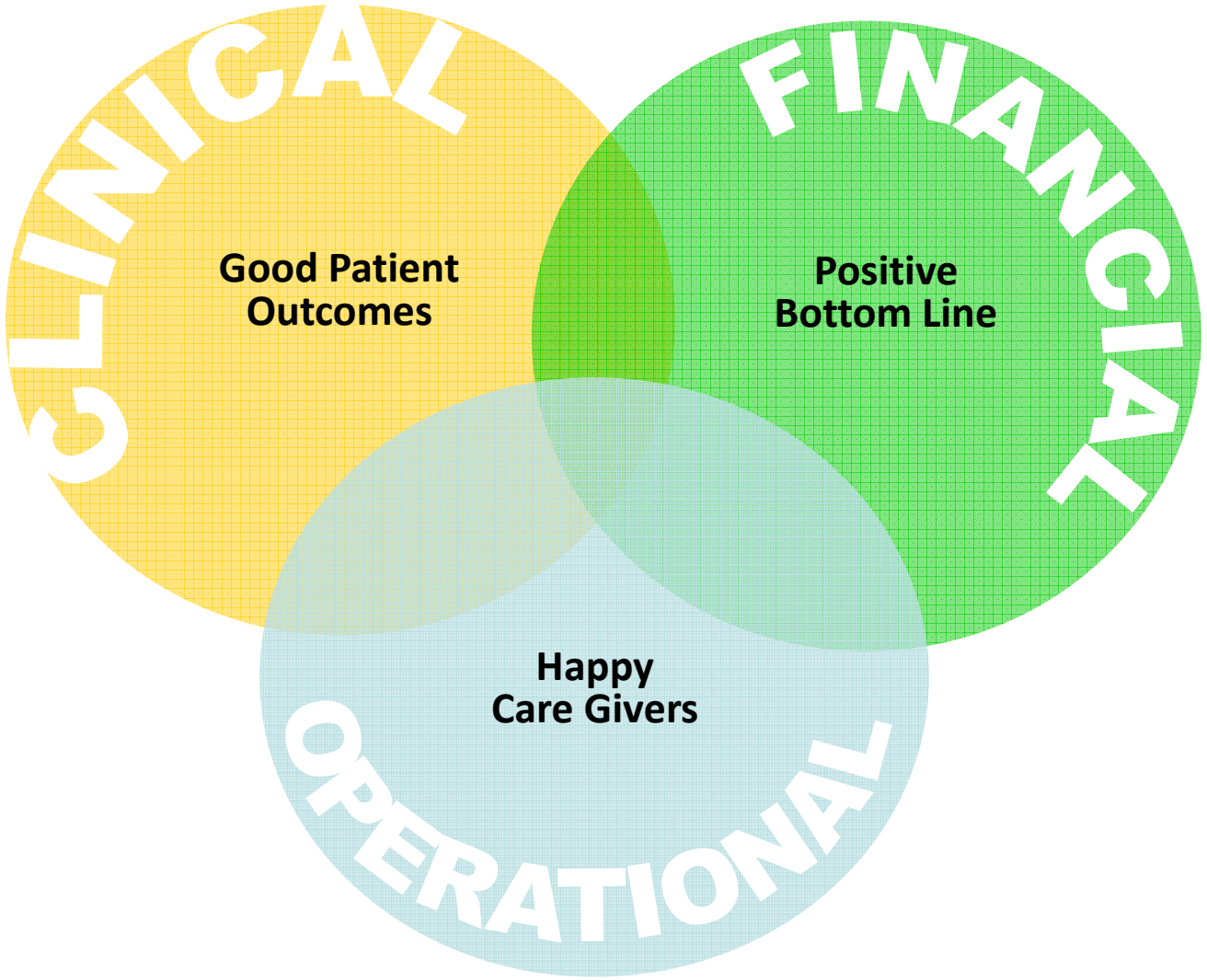
What is Really Important…

Three Fundamental Goals



CDRH Postmarket Strategy – launched 9/2012

- September 10: Strengthening the National Medical Device Postmarket Surveillance System
- September 11: MDEpiNet 2012: Partnership for Building Global Medical Device Surveillance Capabilities
- September 12-13: Leveraging Registries with Medical Device Data for Postmarket Surveillance and Evidence Appraisal Throughout the Total Product Life Cycle

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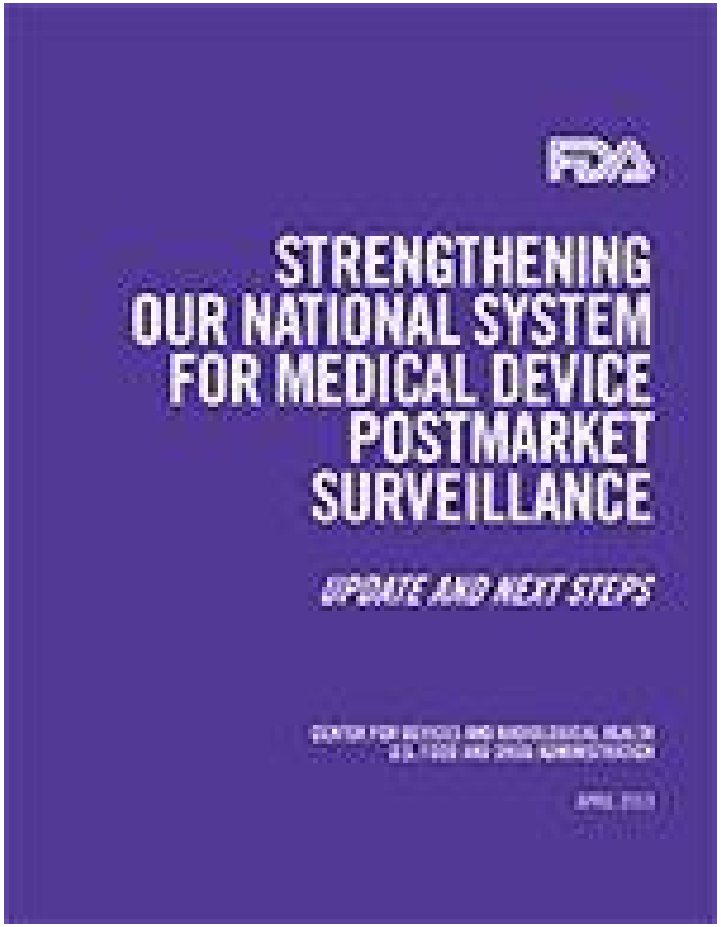
Postmarket Strategy: Update and Next Steps 4/13



- 2013 Implementation Plan
- Postmarket Surveillance Website
- Planning Board
- Registry Task Force

10

Proposed Specific Actions to Strengthen Device Postmarket Surveillance

1) **Establish a UDI System and Promote the Incorporation of UDI into Electronic Health Information**
   - UDI critical for surveillance (including attributes)
   - UDI critical for leveraging distributed data sources
2) **Promote the Development of National and International Device Registries for Selected Products**
   - Need to be linked to other longitudinal data sources for effective longitudinal surveillance

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Proposed Specific Actions to Strengthen Device Postmarket Surveillance

3) **Modernize Adverse Event Reporting and Analysis**
   - Automated methods may enhance case ascertainment

4) **Develop and Use New Methods for Evidence Generation, Synthesis, and Appraisal**
   - Surveillance operating characteristics vary by study design, parameter specification, and data source
   - Need to understand and account for learning curve effects

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Establishing a UDI System: Four Steps

1. Develop a standardized system to create the unique device identifiers (UDI) - a foundational element – unambiguously identifies a specific device at its unit of use

2. Place the human and machine readable UDI on a device, its label, or both

3. Create and maintain the Global Unique Device Identification Database (GUDID)

4. Implementation

3rd Step – GUDID Data
Device Attributes (Examples)

For each DI:

- **Manufacturer, Make/model, Brand/Trade Name**
- **Clinically relevant size**
- **Contact information**
- **Sterility information**
- **Natural Rubber Information**
- **FDA premarket authorization (510k, PMA)**
- **FDA product code (procode)**
- **Marketing Status/date**
- **For single-use**
- **Higher levels of packaging**
- **Rx – OTC**
- **GMDN/SNOMED**

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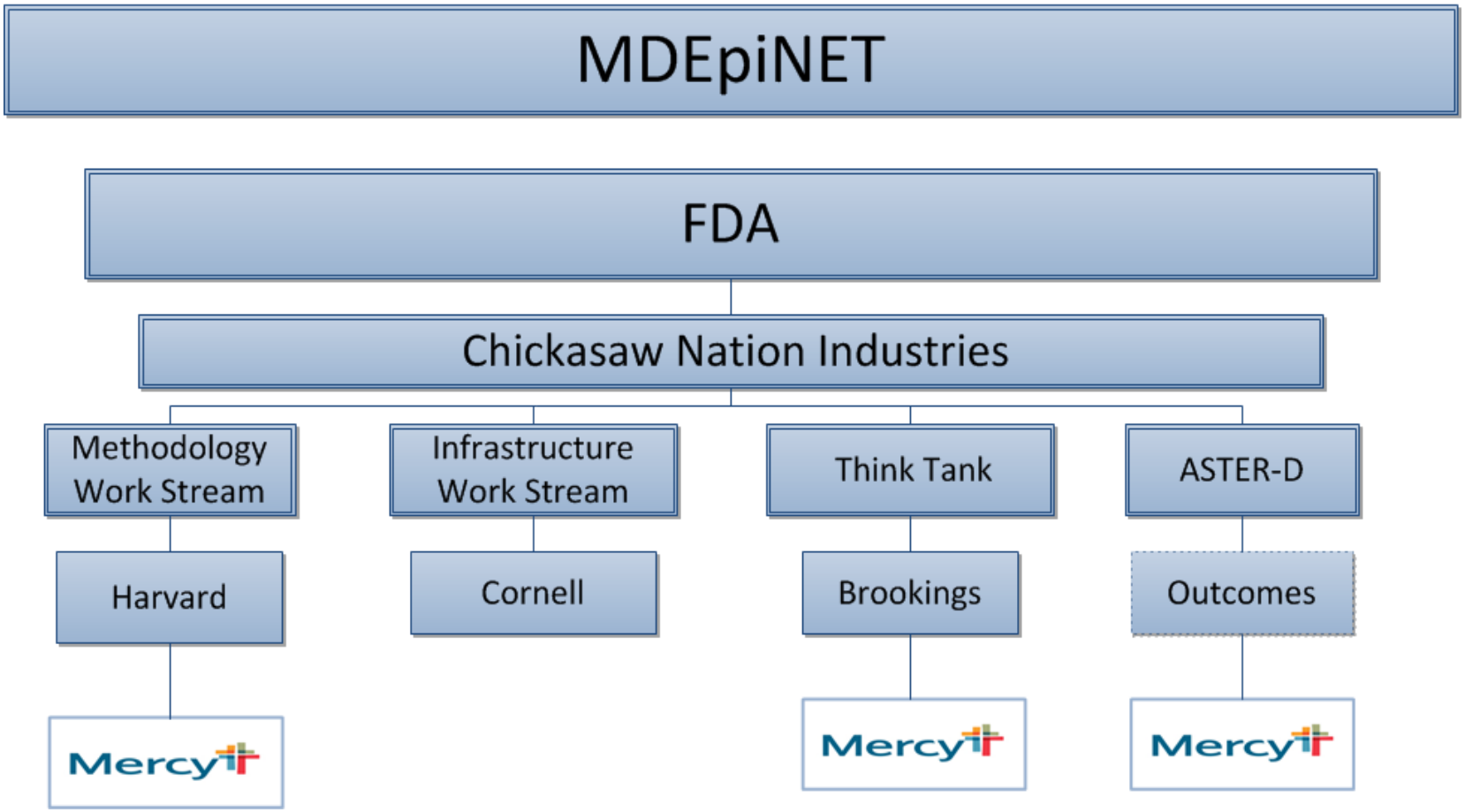
Pertinent Points from the Draft Rule

- **Data must be Human Readable and encoded in an AIDC format**
- **Agnostic as to the machine readable standard: GS1, HIBCC, and ICCBBA (International Council for Commonality in Blood Banking Automation) are all currently recognized.**

FDA MDEpiNet Initiative

MISSION

✓To develop national/international infrastructure and innovative methodological approaches for conducting robust studies and surveillance to improve medical device safety and effectiveness understanding throughout the device life cycle through Public Private Partnership with academia and other stakeholders .


MDEpiNET
FDA
Chickasaw Nation Industries
Methodology Work Stream
Infrastructure Work Stream
Think Tank
ASTER-D
Harvard
Cornell
Brookings
Outcomes
Mercy
Mercy
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UDI Demonstration Project Aims

1. Implement a coronary artery stent UDI-based surveillance system in the EHR in a multi-hospital system (Mercy)

2. Identify obstacles to implementation of UDI in clinical information & to characterize the effectiveness of interventions to overcome them;

3. Assess the validity and utility of data obtained from the EHR and incorporated UDIs for purposes of post-market surveillance

Key Components of UDI Demonstration

- Create **Draft UDIs** & associate with base attributes in the FDA's Global UDI Database (GUDID)
- Create clinically meaningful supplemental **attributes** to be stored in a reference database
- Create **UDI data flow** through ERP to cath lab to EHR to UDI data set
- Create UDI fields in the **CathPCI Registry**
- Perform **studies** to demonstrate validity and reliability of data
- Identify **obstacles** to incorporating UDIs into EHR and explore solutions

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What we needed to do

- **Create *partnerships* to establish a UDI system**
  - *Health Systems* (HTG: Mayo, Geisinger, Intermountain, Kaiser-Permanente, Mercy)
  - *Professional Societies* (American College of Cardiology and the Society for Cardiovascular Angiography & Interventions)
  - *National Registry* (National Cardiovascular Data Registry's CathPCI Registry)
  - *Industry* (Abbott, Boston Scientific, Medtronic)
  - *FDA*

- **Propose appropriate *governanc*e of the UDI system for long term sustainability**

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So, where are we?
Project Status Report

- Began work on system design: April, 2012
- Expert Work Group Meeting and teleconferences: August-November, 2012
- Stood up SUDID: October, 2012
- Implementation of stent scanning and data capture: November 1, 2012
- Stood up UDI Research & Surveillance Database (UDIR): February, 2013
- Currently optimizing UDIR
- Performing preliminary analyses

The Expert Work Group

- **The Expert Panel: Five interventional cardiologists appointed in conjunction with ACC and SCA&I**

- **"*Ex officio*" members**
  - FDA representatives
  - Coronary Stent manufacturer representatives
  - HTG system representatives
  - NCDR representatives

Expert Work Group Members

Expert Panel Members

James Tcheng, MD (Chair), Duke University Medical Center

Kirk Garratt MSc, MD, Lenox Hill Heart and Vascular Institute of New York

Kalon K.L. Ho, MD, MSc,, Beth Israel Deaconess Medical Center

John McB. Hodgson, MD, FACC, FSCAI, Technology Solutions Group

J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

FDA Representatives

Jay Crowley, Senior Advisor for Patient Safety

Behnaz Minaei, Public Policy Analyst

Terrie L. Reed, MSIE, Director of Informatics

Madris Tomes,UDI External Program Manager

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Expert Work Group Members

Health System Representatives

Mercy Health

Joseph P. Drozda, Jr., MD (Principal Investigator)Director of Outcomes Research

Curtis Dudley, Vice President, Integration Technology Solutions and Account Implementation

Paul Helmering, Executive Director, Enterprise Architecture

Priscilla Smith, Project Development Specialist

Mitzi Sutton, Director, Operations Mercy Health Research

Mayo Clinic

Joseph Dudas, Vice Chair, Category Management

Robert F. Rea, MD, Cardiology

Intermountain Healthcare

J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

Geisinger Medical Center

James Blankenship, MD, Director, Cardiology

Kevin Capatch, Director of Supply Chain Technology and Process Engineering

Deborah Templeton, R.Ph, MHA, Vice President, Supply Chain Services

Kaiser Permanente

Scott Adelman, MD, FACC, Chair, Cardiology Technology Committee, Northern California

Laurel Junk, Vice President, Supply Chain

Expert Work Group Members

Manufacturer Representatives

Abbott Vascular

Judith Fairchild, Director, AV Quality

Krishna Sudhir, MD, PhD, FRACP, FACC , Divisional VP, Medical Affairs and Product Performance

Boston Scientific Corporation

Dominic Allocco, MD, FACC, Vice President, Clinical, Division of Interventional Cardiology

Medtronic

Roberta Dressen, Vice President, Global Post-Approval Network

Kweli P. Thompson, MD, MPH, Group Vice President of Clinical Research for the Cardiac and Vascular Group

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Expert Work Group Members

Professional Societies

American College of Cardiology

Kathleen Hewitt, Associate Vice President

Society for Cardiovascular Angiography and interventions

Joel Harder, Director for Quality Initiatives and Clinical Documents

NCDR

Nichole Kallas, Associate Director, IT Business Analyst

Tasks for Expert Work Group

- Develop a constrained list of coronary stent clinical attributes to supplement the GUDID attributes (Expert Panel)
- Propose a permanent home for UDI clinical attribute database (SUDID)
- Recommend a governance structure for the SUDID
- Develop a proposal for an organization and processes for ongoing maintenance of the SUDID

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Expert Work Group Outputs

- Constrained list (9) of supplemental coronary stent attributes
- Use cases for UDID in clinical data sets
- Recommendations re governance and operations of Supplemental UDI Database (SUDID)
- Recommendations re broader registry-centered data sharing network for device surveillance

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Attribute	Definition	Parameter	Data Type
Length	Nominal length per manufacture specification	Fractional dimension in mm	4 significant digits, w/1 precision
Diameter	Nominal (inner) diameter per manufacturer specification	Fractional dimension in mm	4 significant digits, w/2 precision
Non-conventional Property	Stent having nonconventional design, variable or multiple length/diameter parameters	Covered stent Bifurcation Stent Tapered Stent	Alphanumeric
Structural Material	Composition of principal structural element	Constrained list e.g. L605 cobalt chromium -- Constrained list to be developed	Alphanumeric
Coating(s)	Non-Structural material covering surface of structural element	Constrained list -- Constrained list to be developed --Need to handle multiples --name that would be mostly referenced --start with what is in the IFU --accommodate multiple coatings	Alphanumeric
Drug(s)	Active agent released from stent	NDC directory (default) --Use name if no applicable NDC code—do it uniformly	Alphanumeric
Strut Thickness	Maximum nominal thickness of stent struts on a radius from the center of the stent	Dimension in microns	4 integer digits
Surface to Artery Ratio*	Percentage of the surface area of the artery covered by the stent at nominal expansion of the stent		3 significant digits, w/1 precision
Expansion Method	Method used to achieve nominal stent deployment	Balloon Self	Alphanumeric
MRI Compatibility	MRI compatibility category per testing	4 categories per existing standard: --Safe --Conditional --Unsafe --Not tested	4 Categories

*This attribute was originally selected by the Expert Panel but subsequently withdrawn

SUDID = Supplemental Unique Device Identifier Database; IFU = Instructions for Use; NDC = National Drug Code; MRI = Magnetic Resonance Imaging

Table 3: SUDID Clinical Attributes and Parameters

Attribute	Definition	Parameter	Data Type
Length	Nominal length per manufacture specification	Fractional dimension in mm	4 significant digits, w/1 precision
Diameter	Nominal (inner) diameter per manufacturer specification	Fractional dimension in mm	4 significant digits, w/2 precision
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Structural Material	Composition of principal structural element	Constrained list e.g. L605 cobalt chromium -- Constrained list to be developed	Alphanumeric
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Use Cases for Attributes

Use Case Name	Description	Attributes Needed (GUDID/SUDID)
Point of Care UDI Scan	Query device attributes immediately prior to use	GUDID & SUDID
Catalog/device ordering	Ordering by attribute, device, substitution, tracking devices in disasters	GUDID & SUDID
Medical Documentation	Procedure reporting, health care communication	GUDID & SUDID
EHR/Patient Portal	Attributes stored as data outside of procedure report, patient education	GUDID & SUDID
Queries (by attribute)	Support for process measurement, QI projects	GUDID & SUDID
Extending indications for use	Support of alternative processes for device labeling	GUDID & SUDID
Comparative effectiveness research	Support of comparative effectiveness	GUDID & SUDID
Registries	Process, performance, quality outcomes, education, performance improvement Continuing Medical Education	GUDID & SUDID

Use Cases for Attributes

PHR/Consumer	Information to patient, education, public communication, healthcare advocates	GUDID & SUDID
Supply chain management	Competitive bidding by attributes	GUDID & SUDID
Advance notice of expiration	Inventory management	GUDID
Administrative uses	Asset and financial management	GUDID
Device Recall	Easily identify patients who received the affected lots and locate unused product in clinical use areas	GUDID
Federated Data Exchange	Increased ability to report outcomes across products	GUDID
Adverse Event Reporting	Increased ability to report adverse events and outcomes	GUDID
Anti-counterfeiting	Increased protection against fraud	GUDID
Tracking of patients with multiple devices	Allow providers to learn information about prior device implantation, even when prior medical records are not available	GUDID
Federal (post-market surveillance)	Specify device exposure and usage for linkage with safety and research outcomes	GUDID

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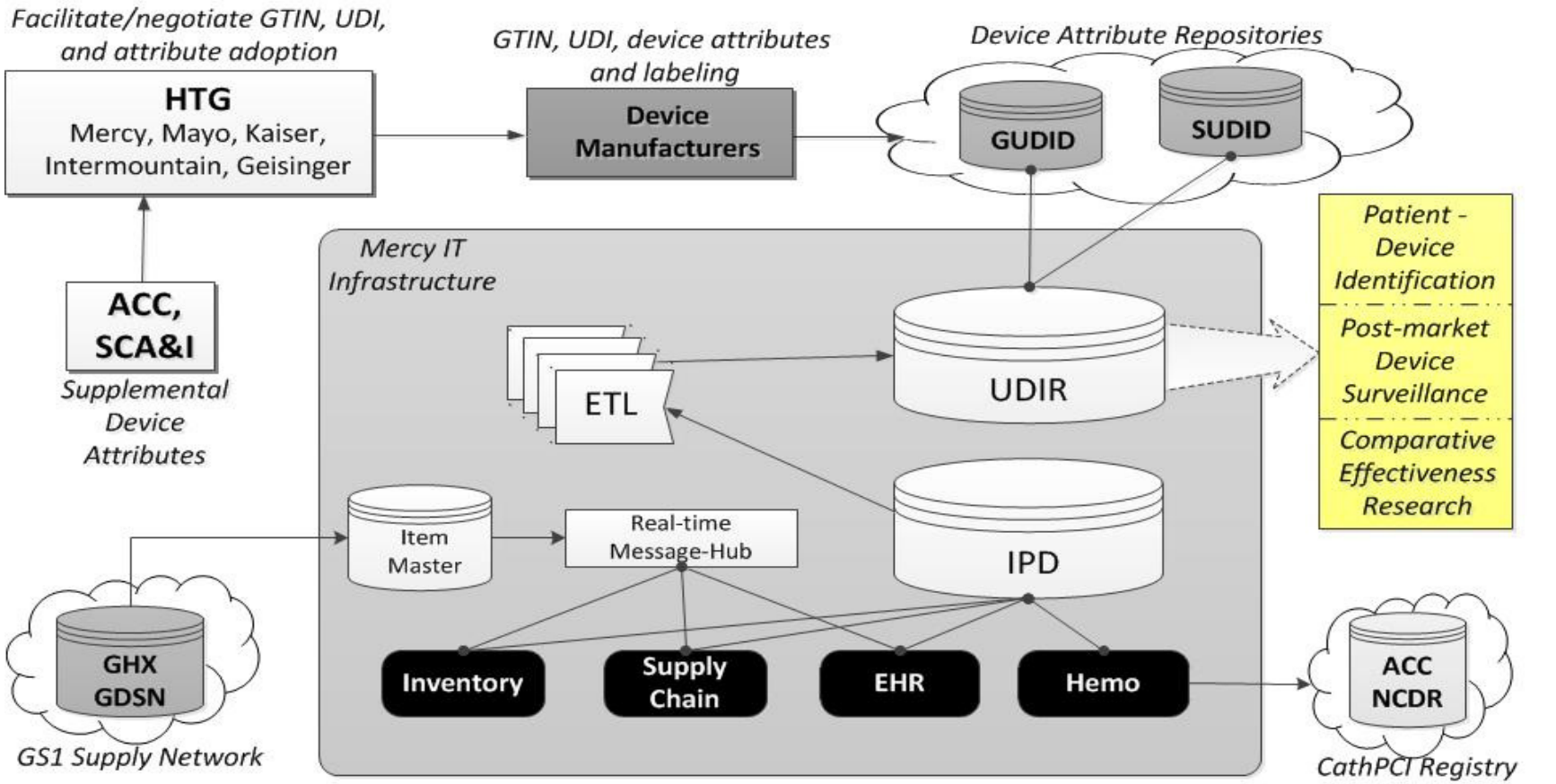
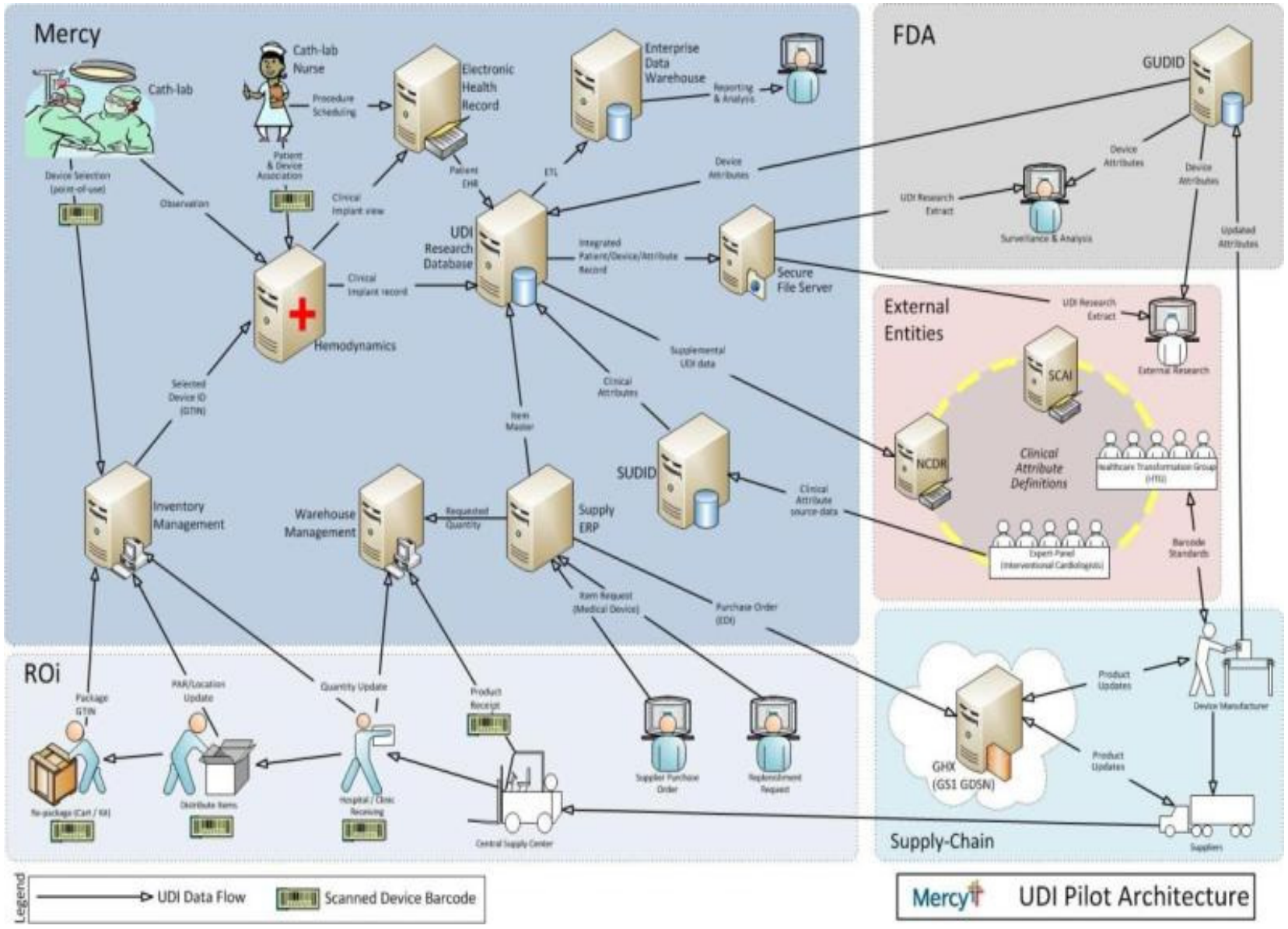
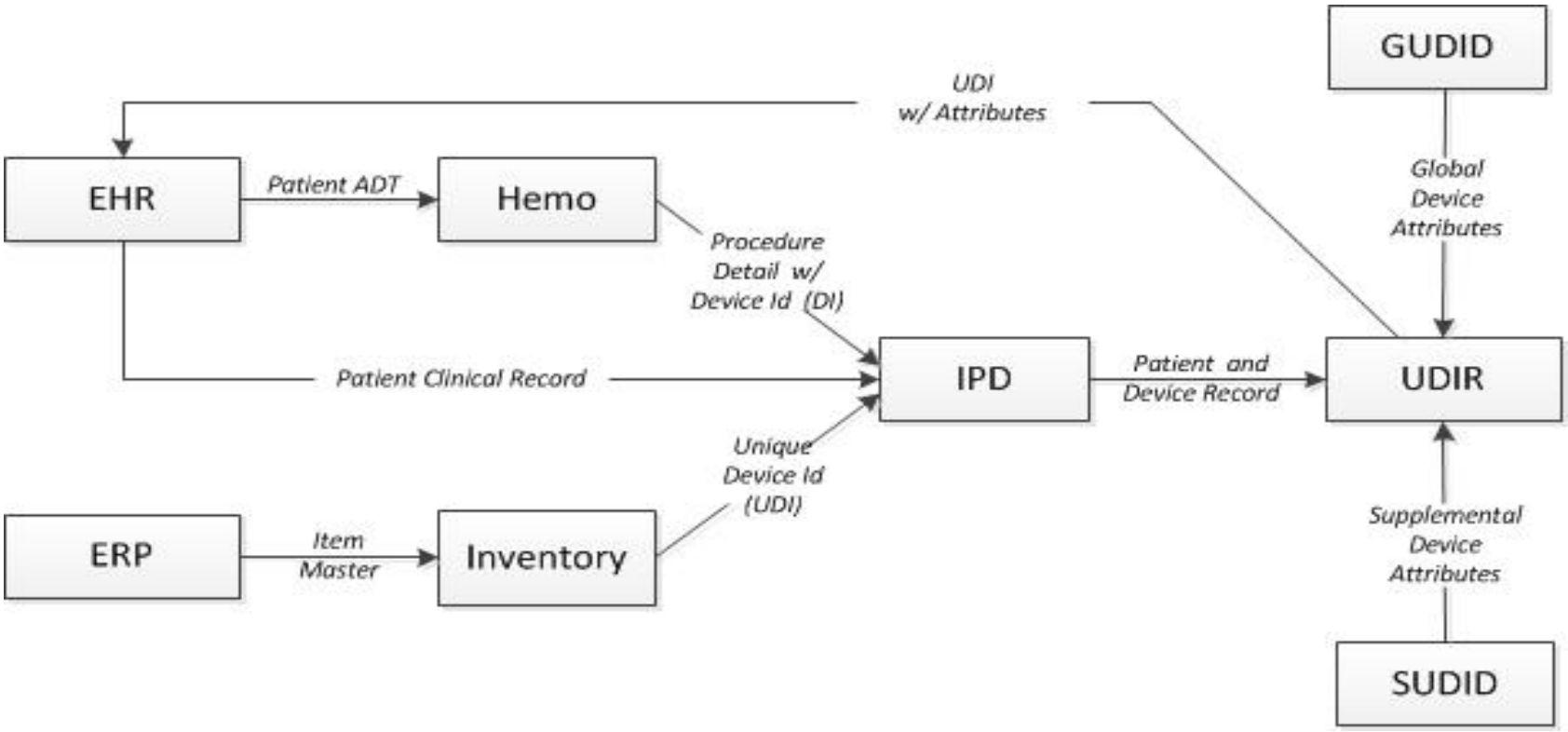
UDI Demonstration Project
High Level Architecture



Glossary: UDIR = UDI Research database GUDID = Global UDI Attributes SUDID = Supplemental UDI Attributes
IPD = Integrated Patient Datamart ETL = Extract/Transform/Load of data


Mercy
Cath-lab
Cath-lab Nurse
Procedure Scheduling
Electronic Health Record
Enterprise Data Warehouse
Reporting & Analysis
Device Selection (point-of-use)
Observation
Patient & Device Association
Clinical Implant view
Patient EHR
ETL
Device Attributes
UDI Research Database
Integrated Patient/Device/Attribute Record
Secure File Server
Clinical Implant record
Hemodynamics
Supplemental UDI data
Clinical Attributes
Item Master
Selected Device ID (GTIN)
Inventory Management
Warehouse Management
Requested Quantity
Supply ERP
SUDID
Clinical Attribute source data
Item Request (Medical Device)
Purchase Order (EDI)
ROi
Package GTIN
PAR/Location Update
Quantity Update
Product Receipt
Supplier Purchase Order
Replenishment Request
Central Supply Center
FDA
GUDID
Device Attributes
UDI Research Extract
Surveillance & Analysis
Updated Attributes
External Entities
UDI Research Extract
External Research
SCAI
NCDR
Clinical Attribute Definitions
Healthcare Transformation Group (HTG)
Expert Panel (Interventional Cardiologists)
Barcode Standards
Supply-Chain
GHX (GS1 GDSN)
Product Updates
Device Manufacturer
Suppliers
Legend
UDI Data Flow
Scanned Device Barcode
Mercy
UDI Pilot Architecture

Single EHR UDI Tracking System Data Flow



- *Global Unique Device Identification Database (GUDID)*
- *Electronic Health Record (EHR)*
- *Enterprise Resource Processing (ERP)*
- *Unique Device Identification Research Database (UDIR)*
- *Supplemental Unique Device Identification Database (SUDID)*
- *Integrated Patient Dataset (IPD)*
- *Merge Hemodyamic Software (Hemo)*

Obstacles

- **Technical: Biggest problem so far is Merge**
- **Agreeing on:**
  - Industry-wide standards
  - Device attributes
  - Organizational infrastructure and support for designing and maintaining a UDI system
  - The business case for all stakeholders

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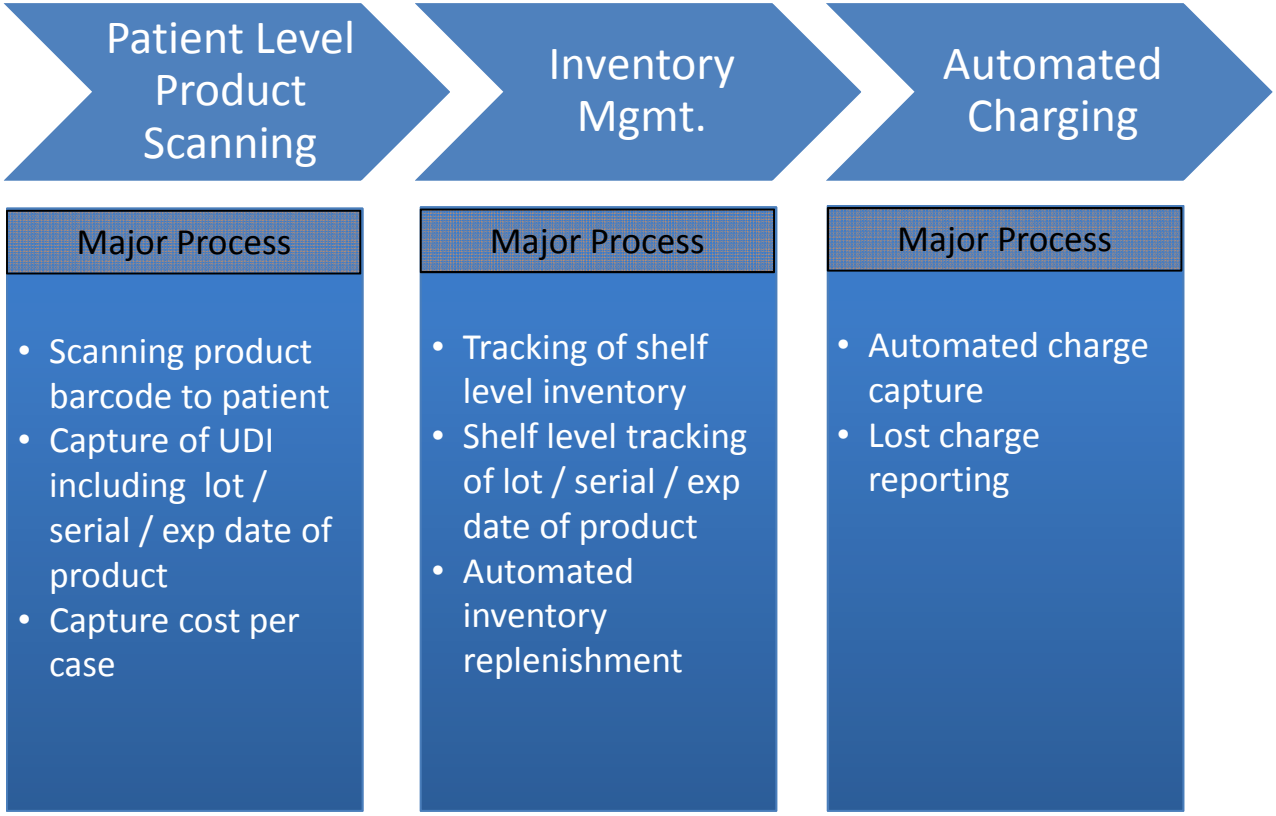
Performance Solutions - What we did…

Changes to Cath Lab Process

- The UDI project required us to make changes to how the Cath Lab process works

- The changes we made improved many aspects of the workflow in the Cath Lab

Performance Solutions - What we did…



Goal: Enable capture of the UDI to the patient… Apply automation to highly manual process

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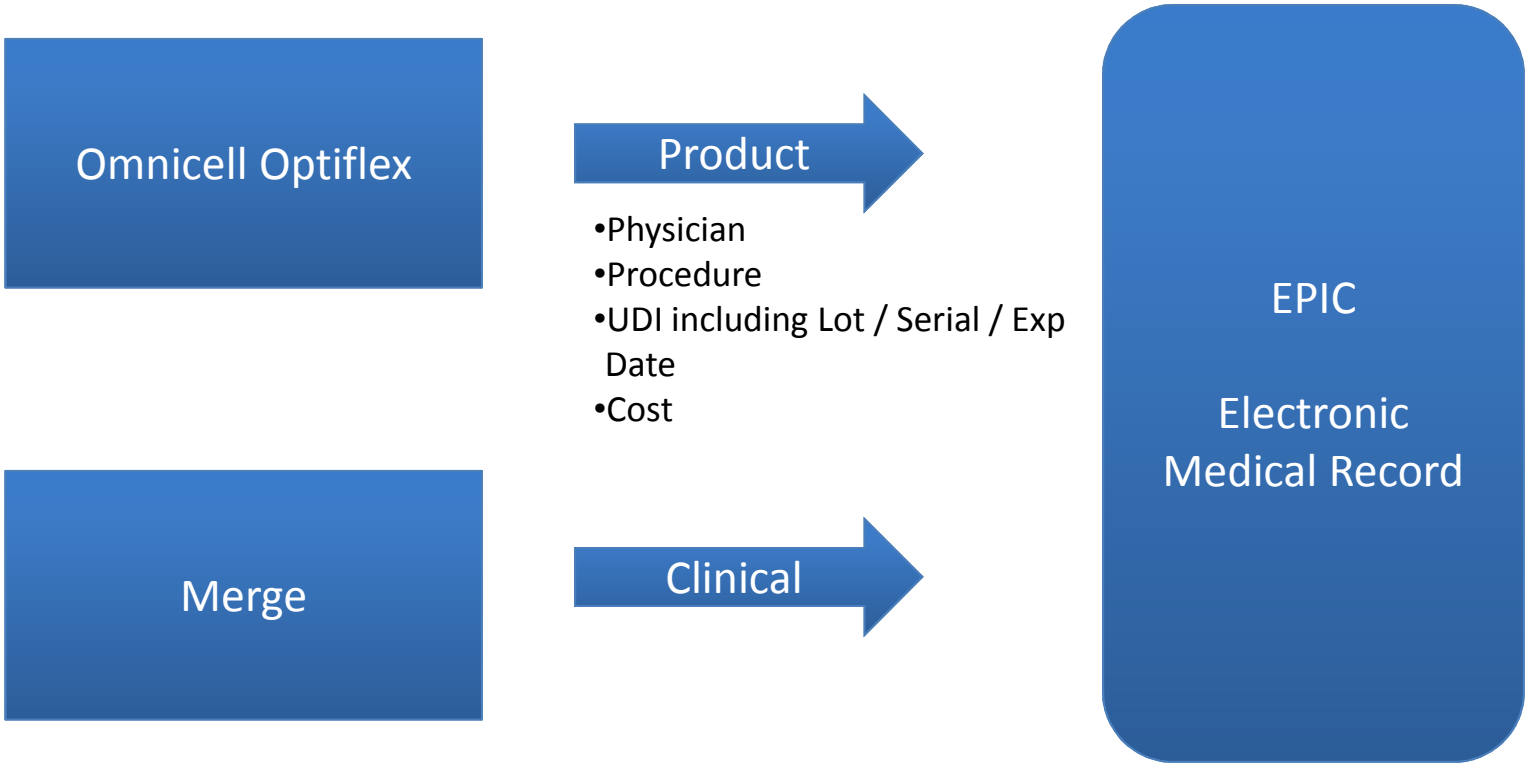
Performance Solutions - What we did…

Information Flow



Several key data points are now captured per patient that have never been captured before… These data point will lead to other improvement opportunities

UDI Research & Surveillance Database (UDIR)

- **A functional database for device surveillance and research that is the ultimate output of the Demonstration Project**
- **Contains:**
  - Key clinical data from the EHR
  - SUDID attribute data
  - GUDID attribute data
- **Provides:**
  - Exposure data
  - Adverse outcome data
  - Evaluations by stent brand and by attribute

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Example Use Case

FDA Query:

- 10 cases of heart attack & death within 3 months of stent X implant reported to FDA (UDIs of involved stents provided)
- Request all data on stent X:
  - UDI of each implanted stent and associated GUDID and SUDID attributes
  - Date of implant
  - Baseline (time zero) patient characteristics—
    - Patient demographics including date of birth, sex, race/ethnicity
    - All available laboratory values
    - Key implant data including the coronary artery in which the stent was implanted along with all other coronary stents implanted at the time of the same procedure along with their UDIs
  - All subsequently collected patient variables including laboratory values with associated dates
  - All patient outcomes/safety events defined as Major Adverse Cardiovascular Events (MACE) and dates of their occurrence
    - For MACE that involve repeat catheterization, include UDIs and attributes on any coronary stents implanted during the procedure along with all available laboratory values.

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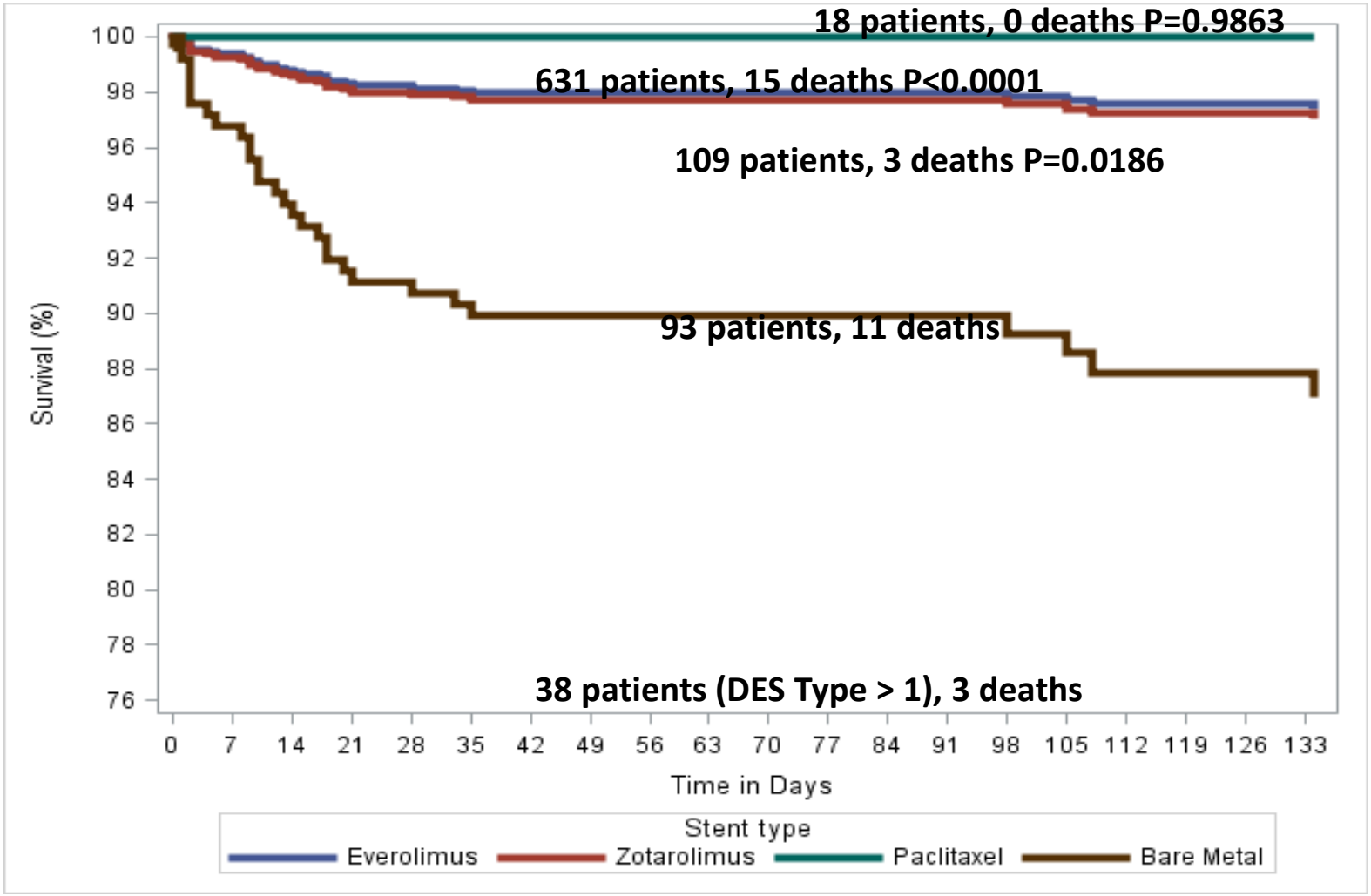
Device attribute: Drug
Patient characteristics: All
Outcome: Mortality



Where do we go from here?

- Complete current Demonstration Project by 12/31/13
- Continue planning for “UDI Phase 2”

Vision for UDI Phase 2

Create a robust system of medical device surveillance and research to support FDA and physicians in keeping patients safe and to enhance research on innovative technologies.

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UDI Phase 2

- ***Purpose*:**

  Build a national network of UDI enabled EHR data sets around national registries for device surveillance and research.

- ***The UDI Alliance:***
  - HTG Health Systems (Mercy, Mayo, Geisinger, Intermountain, and Kaiser)
  - National medical societies and registries (ACC, SCAI/NCDR)
  - Industry (Medtronic, Abbott, Boston Scientific)
  - Consumer groups/patient representatives)

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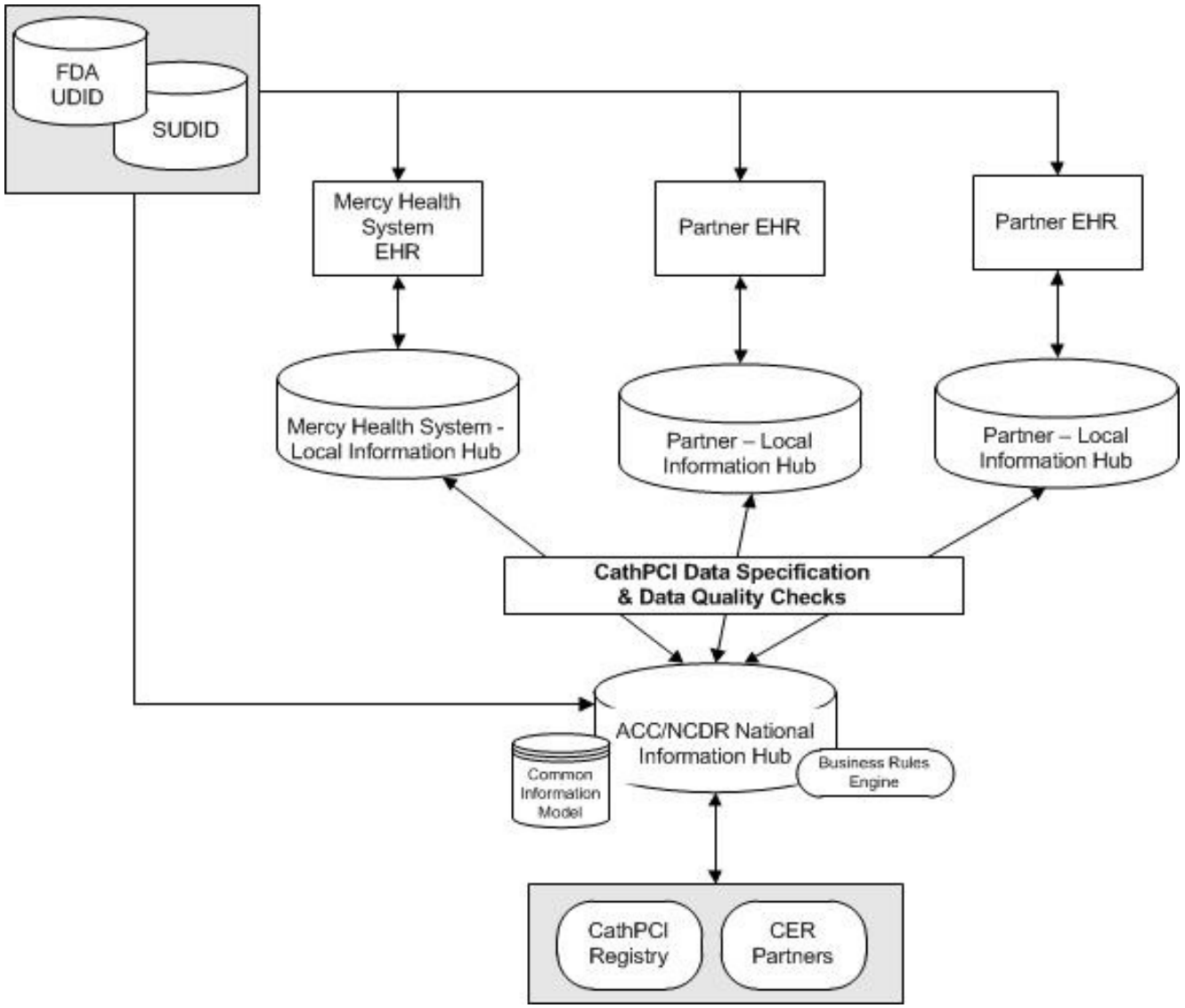
Coronary Stent Distributed Data Sharing Network



Thanks!

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