HTG Summit 2019 Agenda

Day 1 – Wednesday, October 23, 2019

Time	Topic	Presenter/Facilitator
8:00 am - 8:30 am	**Registration & Breakfast**	
8:30 am - 9:00 am	Welcome and Introduction to the FMOLHS Data Standards Journey	Sandi Michel
9:00 am - 9:30 am	FMOLHS Supply Chain Vision	Bill Mosser & Dr. Richard Vath
9:30 am - 10:30 am	SCANH Competition Summary	Dr. Anne Snowdon
10:30 am - 10:45 am	Break	
10:45 am – 11:15am	FDA Updates	Behnaz Minaei
11:15am – 12:00pm	AHRMM LUC Initiatives	Nancy LeMaster
12:00 pm - 1:00 pm	Lunch	
1:00 pm – 3:00 pm	Collaboration Sessions: Topic 1: Barcode scanning at the Point of Care Topic 2: UDI-DI (or GTIN) Changes Topic 3: Interoperability Topic 4: GLN Usage and Benefit	Four Group Session Leader & Scribe
3:00 pm - 5:00 pm	Tours	Brittney Sprague
6:00 pm - 8:00 pm	Top Golf Networking Event	Top Golf

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Day 2 – Thursday, October 24, 2019

Time	Presentation	Presenter
8:00 am - 8:30 am	Breakfast	
8:30 am - 8:45 am	Day 2 Kick-Off	Sandi Michel
8:45 am - 9:45 am	Solution Providers Roadmaps	
9:45 am - 10:15 am	Data Standards Update	Jeff Holzman
10:15 am-10:30 am	Break	
10:30 am-12:00 pm	Collaboration Sessions: Topic 1: Barcode scanning at the Point of Care Topic 2: UDI-DI (or GTIN) Changes Topic 3: Interoperability Topic 4: GLN Usage and Benefit	Four Groups Leader & Scribe
12:00pm - 1:00pm	Lunch	
1:00 pm - 1:30 pm	BUILD Update	Dr. Jove Graham
1:30 pm – 2:00 pm	DSCSA and Blockchain Update	Bob Celeste
2:00 pm – 3:45 pm	Report Out and Action Steps	Four Groups Leader & Scribe
3:45 pm - 4:00 pm	Wrap Up and Send Off	FMOLHS / HTG

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Welcome to the 9th Annual HTG Summit

October 2019

Mercy

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM

Geisinger

KAISER PERMANENTE®

Intermountain® Healthcare

MAYO CLINIC

Your Hosts for the 9th Annual HTG Summit

Franciscan Missionaries of our Lady Health System
Executive Team
Sandi Michel, Director of Supply Chain Strategy
Emmett Robbins,
Brittney Sprague,
James Phillips,
Michelle Keller,

Intermountain Healthcare
Jeff Martin
Cynthia Shumway

Mayo Clinic
Kathy Anderson
Robert Badzinski
Sara Erickson
Kay Hysell
Dan Schmitz
Erin Williams

Geisinger
Jun Amora
Kevin Capatch
Tasha Gowin
Jove Graham

Kaiser Permanente
Karen Dean

Mercy
Curtis Dudley
Lynn Sandoval
Joe Schmitz
Kelly Wibbenmeyer
Betty Jo Rocchio

Associate Former HTG–Matt Mentel

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Your Location Hosts for the 9TH Annual HTG Summit

Franciscan Missionaries of our Lady Health System Executive Team
Bill Mosser, Vice President of Supply Chain,
Dr. Richard Vath-Chief Executive Officer,
Darrin Montalvo, EVP, Chief Operating Officer,
Jeff Limbocker-EVP, Chief Financial Officer
Hunter Richardson- SVP, Chief Human Resources Officer

Franciscan Missionaries of our Lady Health System Supply Chain Team
Sandi Michel, Director of Supply Chain Strategy
Emmett Robbins,
Brittney Sprague,
James Phillips,
Michelle Keller,

Franciscan Missionaries of our Lady Health System Administrative Team
Angela Huffines
Meagan Jarreau
Kellie Penton
Cristo Rey, Baton Rouge Franciscan High School Intern

St. Dominic's Health Services
Chrissy Fortenberry
Shelia Norwood
Emily Zuvic,

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WELCOME TO THE ANNUAL HTG SUMMIT AT FMOLHS, BATON ROUGE

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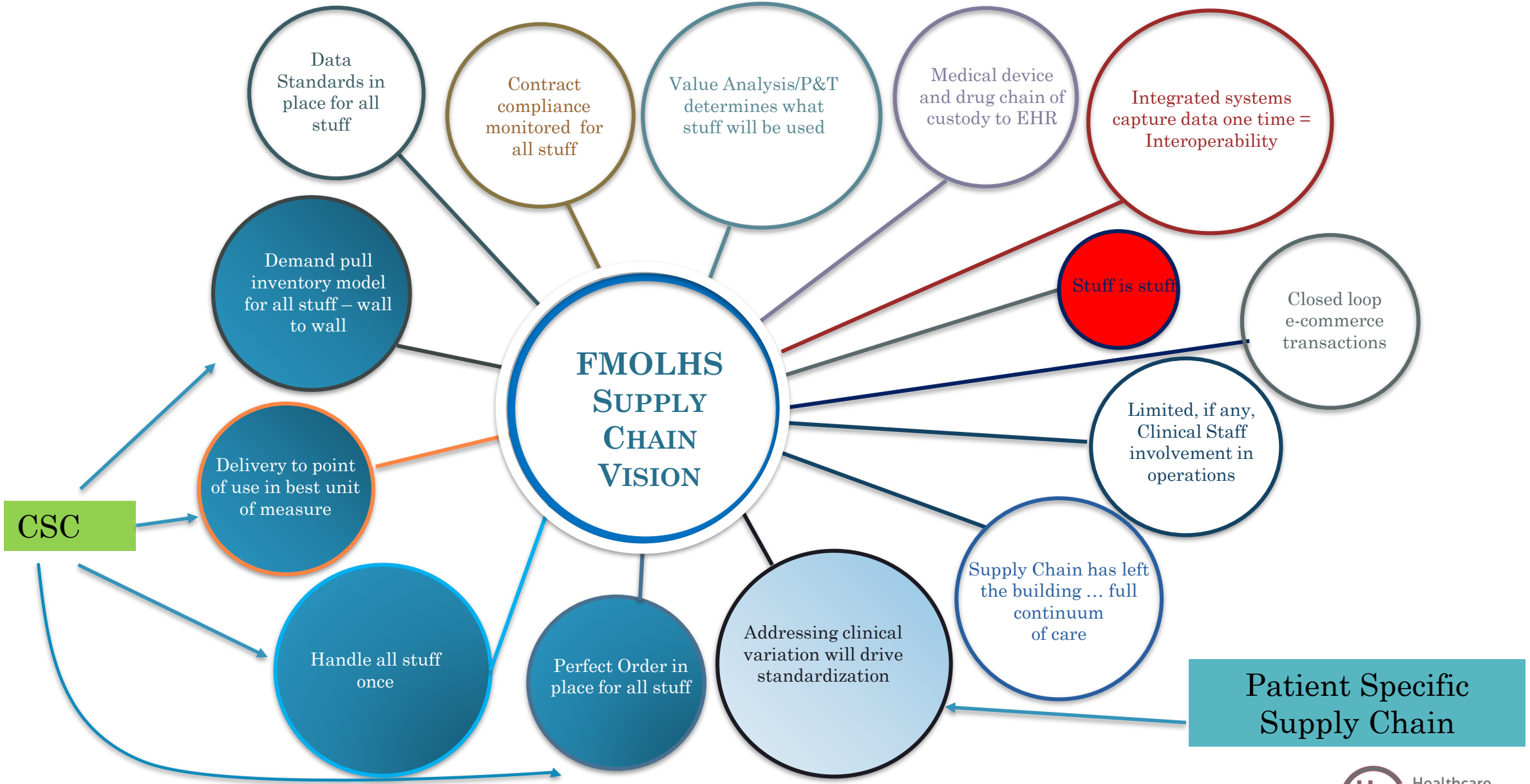
FMOLHS Leadership

- WELCOME to Healthcare Transformation Group
- Bill Mosser, Vice President of Supply Chain
- Franciscan Missionaries of Our Lady Health System

Strategic Supply Chain Principles



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FMOLHS Clinically Integrated Demand Pull Inventory Model

LOGISTICS

Franciscan Missionaries of Our Lady Health System

Y

Starts here at point of care!

I

N

Contract Center

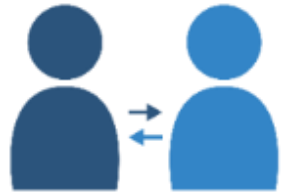
Procurement Suite

Virtual Item Master

Lawson Purchase Order

850/855/856/810/820

Perfect Order



Trading Partner

- Full Use of GS1 Data Standards
- GLN, GTIN, UDI & Bar Coding

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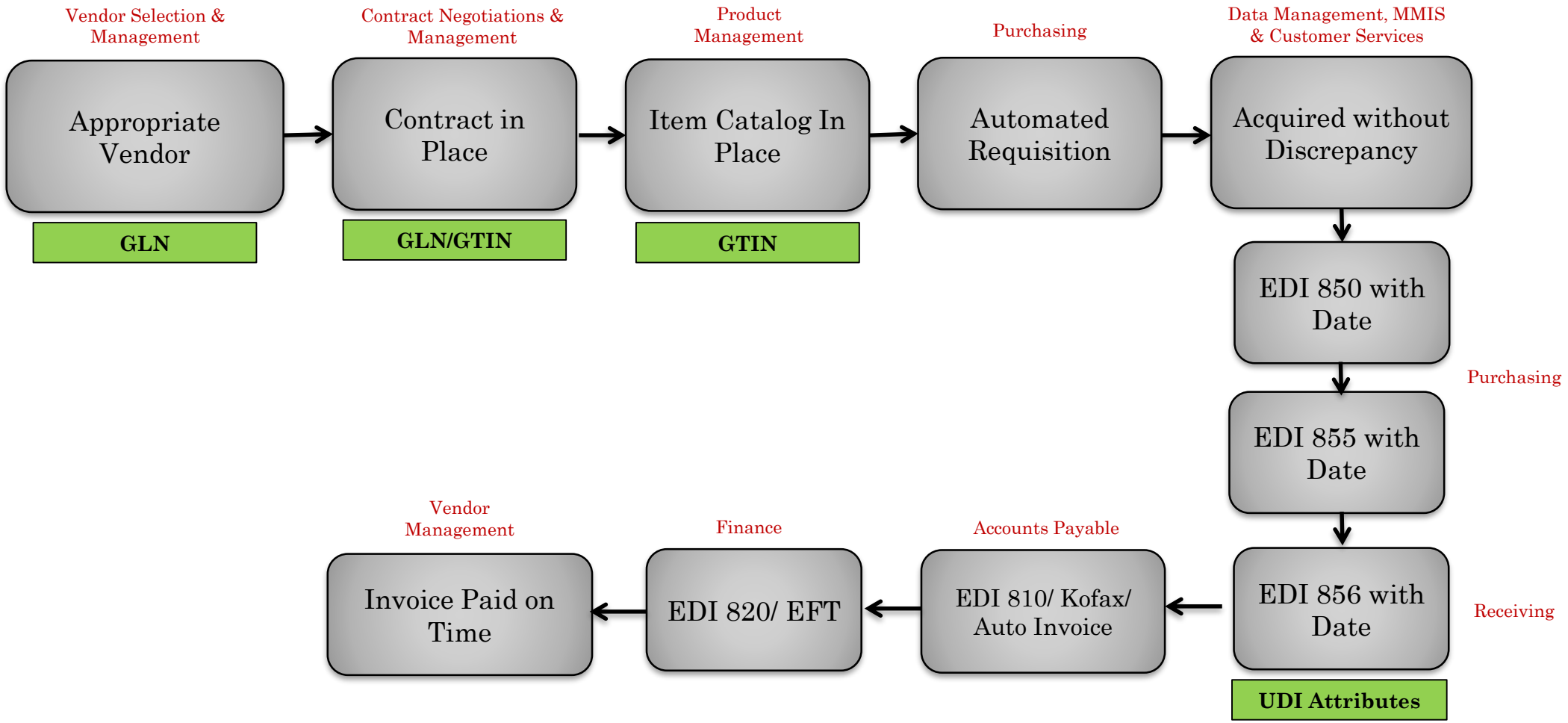
P2P : The Perfect Order Process Flow



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SCAN Health: 2019 Update on Design Competition and Maturity Tool

Dr. Anne Snowdon, BScN, MSc, PhD, FAAN
Professor, Strategy and Entrepreneurship
Academic Chair, World Health Innovation Network (WIN)
Scientific Director & CEO, Supply Chain Advancement Network in Health (SCAN Health)
Odette School of Business

About SCAN Health

In 2017, the Government of Canada, Networks of Centres of Excellence of Canada (NCE) provided $1.6 million over four years (2017-2021) to create SCAN Health. SCAN Health is an International Knowledge Translation Platform (NCE-IKTP) funded to accelerate knowledge translation and address key problems, challenges and opportunities of high strategic importance for health systems in Canada and around the globe.

NCE-IKTP Program: Supports international collaborations between networks, centres, consortia and their partners, with the goal of accelerating the achievements of researchers and the implementation of their work.

Knowledge Mobilization: Specific activities and tools designed to put available, evidence-based knowledge into active service by creating impacts that benefit society.

SCAN Health Mission: To develop an International Knowledge Translation Platform to mobilize expert knowledge and research evidence to inform and support health systems to accelerate, scale and measure health system supply chain transformation.

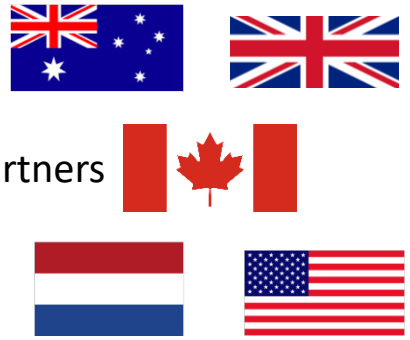
SCAN Health Vision: To advance global capacity to adopt and scale best practices in healthcare supply chain to offer traceability of products and care processes from bench to bedside to patient outcomes.

Our Global Network

SCANH
Supply Chain Advancement Network in Health

Expert Advisory Council (10 Members)

Over 100 partners



3 Working Groups:

- Knowledge Translation WG
- Leadership Capacity Building WG
- Metrics and Impact WG

Board of Directors (13 Members)

- Executive committee
- Finance and Audit committee
- Governance and HR committee

Our Strategic Initiatives

SCANH
Supply Chain Advancement Network in Health

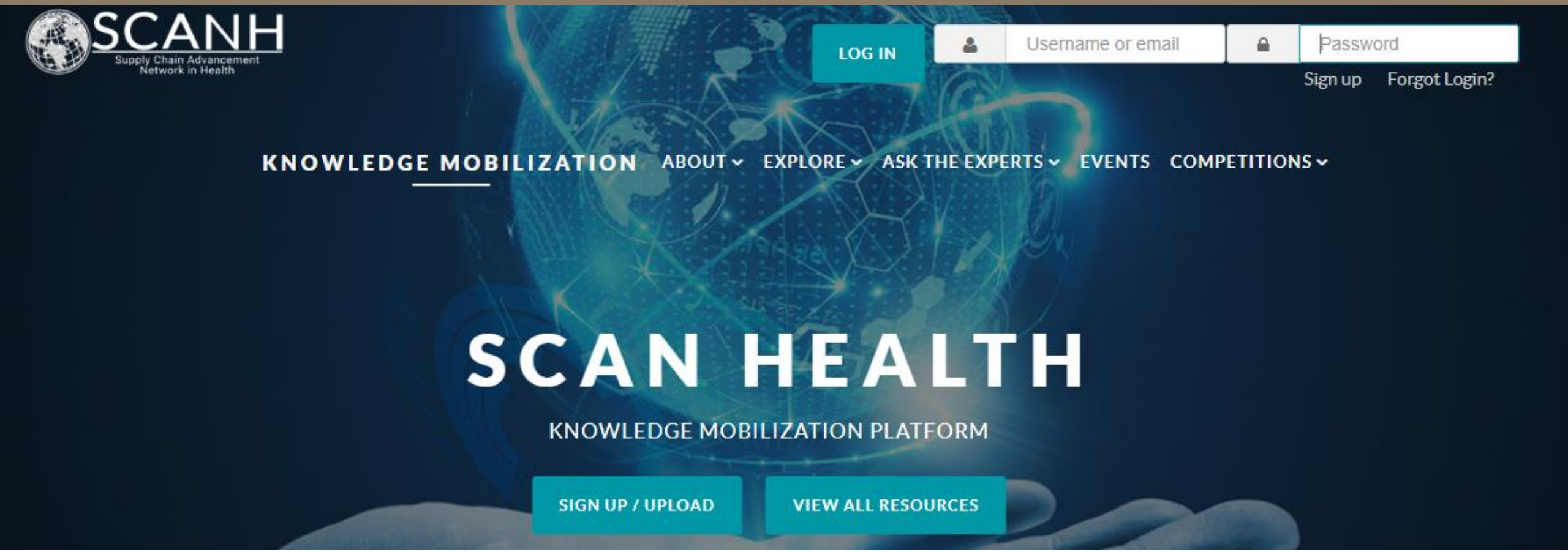
1. **Global Networking Event:** Our annual networking event brokers relationships and fosters collaboration on supply chain initiatives and projects, creating dialogue focused on key challenges and priorities for health systems.

2. **Knowledge Mobilization Platform**: Online learning platform enables partners to come together on key priorities and learning opportunities to profile “best practice” achievements in supply chain transformation in health systems.

3. **Business Case Competition:** Provides students with the opportunity to build leadership capacity and develop solutions to a real-world health system challenge using supply chain strategy and logistics processes.

4. **Clinically Integrated Supply Outcomes Model (CISOM):** Partnered with HIMSS Analytics, CISOM will guide and measure health system’s progress towards transforming their supply chains. Clinically integrated supply chains enable transparency of real-world data and evidence of value and performance.

5. **Design Competition**: Creates a forum for industry to engage with health systems to design the solutions needed to advance supply chain transformation to support traceability of products linked to patient outcomes.



Become a member by signing up at www.scanhealth.ca

- Post and comment on projects, events, publications, presentations, webinars, podcasts and more
- Access to live and archived “Ask the Expert” webinars
- Consult Experts directly through messaging forums for expertise and strategic advice
- Registration for webinars, events and competitions

The competition launches this winter. Details can be found at www.scanhealth.ca

- Open to teams comprised of 2-4 undergraduate and/or graduate students and a faculty advisor
- Offers student teams the opportunity to connect with industry experts to support their learning and success
- Top three teams awarded cash prizes of $7,500
- Winning team will be announced at HIMSS2020 in March!

Design Competition

2019 Competition Challenge

The 2019 competition partnered with the **Healthcare Transformation Group (HTG)** and sponsored by **Intalere** to achieve *"a single source of truth"* for product data in health systems. Teams were challenged to create an integrated supply chain data infrastructure that fosters seamless information exchange, and enables tracking and traceability of care processes, products used in care, and the patient outcomes achieved.

Design Competition

SCANH
Supply Chain Advancement Network in Health

THE CHALLENGE

The primary objective of this Design Competition is to strengthen supply chain data infrastructures and governance to advance health system performance, quality and safety, in a representative sample of hospitals from small rural access to large IDNs.

The solution must offer:

- a standardized approach that enables the consolidation and synchronization of product data currently held in multiple data registries (GUDID, GDSN and proprietary health system data);
- include a mechanism for analysis (cross referencing) of product data from multiple registries to identify gaps, inaccuracies and inconsistencies; ensure the capacity to efficiently share with brand owners the incomplete or inconsistent data; and
- provide a method whereby manufacturers only enter or update product data in one location/system so that it can seamlessly be shared with all registries and health system partners at the same time.

Design Competition Finalists

Finalists' Solutions

- **TEAM GHX:** Our solution will establish a virtuous cycle of data flowing to the provider that can be accessed to manage a variety of clinical, operational and financial activities, all in support of better quality care at a lower cost.

- **TEAM MERCY/TECSYS:** Our team is proposing a model that works on multiple parameters with a distribution of effort across the front line of service that simultaneously leverages artificial intelligence and a consolidated, cloud master to minimize this bottleneck.

- **TEAM SYMMETRIC:** Our vision for HTG's goal is to continue enhancing our algorithms and create additional reports by utilizing their combined data registries, and to leverage HTG's demand for data and reports to establish formal GDSN workflows to collaborate with data creators on item data sourcing and validation efficiently.

Challenge: Many Stops Along the Way to a Successful Journey

Each stop along the way requires different data attributes, from different sources, for different purposes.

Achieving value at each stop spurs adoption of standard data and processes to deliver value to patients.

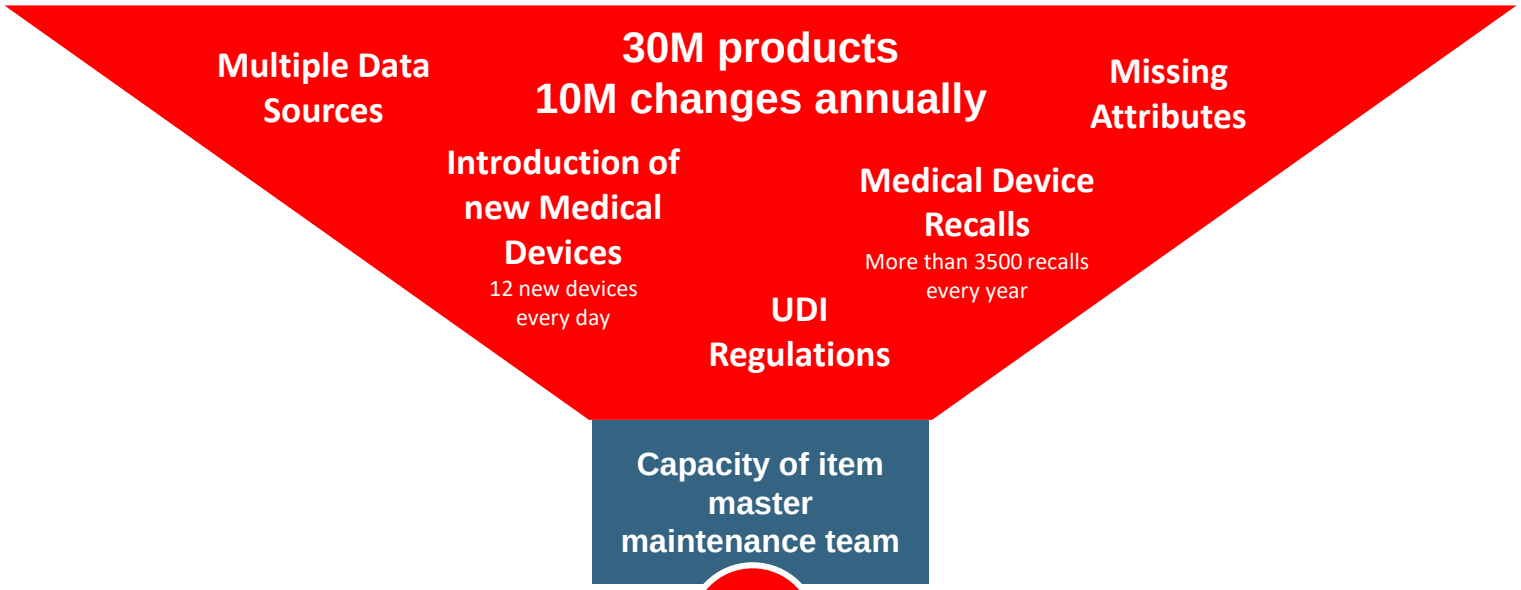
Proposed Solution: "Collective Source of Truth"

Blockchain enabled Data Exchange platform: a continuous learning system of knowledge informed by data about how products are being used.

Virtual Item Master + HashedHealth blockchain technology: clean accurate data set that offers health organizations a data asset that can be monetized

Brings together universal and conditional data elements; conditional elements from production data, contract pricing data, patient clinical factors

Market Problem



Clinically Integrated Supply Chain (CISC) requires 100% capture rate & traceability

Data Capture Challenges Beyond Product Recognition

Unrecognized products	Multiple barcodes on item	Missed items	Unscannable barcodes	Manual input
Due to item master inaccuracy	Confusion around which one to scan	During scanning of multiple items	Wrinkled or scratched barcodes	Error-prone and time consuming

Underlying Inventory Management & Traceability Challenges

- Manual UDI input in multiple applications
- Lack of visibility across inventories
- Manual recall & expiration Management
- Manual replenishment based on tribal knowledge
- Gaps in chain of custody
- Excess inventory & stock wastage
- Revenue leakage

Mercy: Design Solution

Tracked notification to vendor of missing master data with pending status until confirmed by cloud master AI

Vendor

HTG Cloud Master With AI

Point-of-Use hub

Prompt user for missing data

Reply with missing data

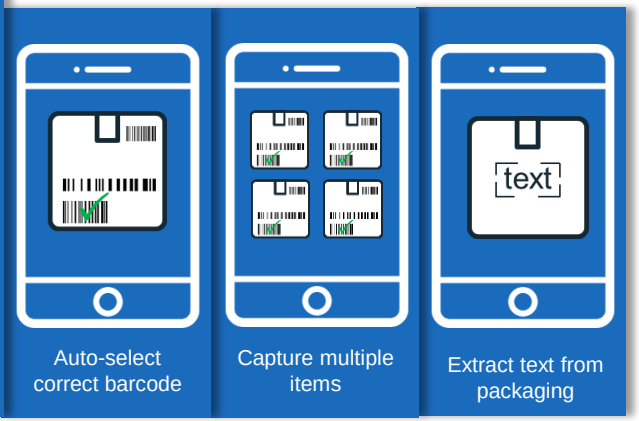
Utilization guidance

Captured item linked to pathway

Prompt user for utilization feedback

Feedback to value analysis team

Computer Vision



Auto-select correct barcode

Capture multiple items

Extract text from packaging

ERP

EMR

PO

Requisition

Item linked to patient/case

- Clinical Supply Documentation
- UDI Tracking & GS1 Capable
- Recall & Expiration Management
- Inventory Optimization
- Replenishment
- Chain of Custody
- Charge Capture
- Case Costing Analytics

Software product: data scrubbed from from > 70 sources

- consolidates all product data across many sources

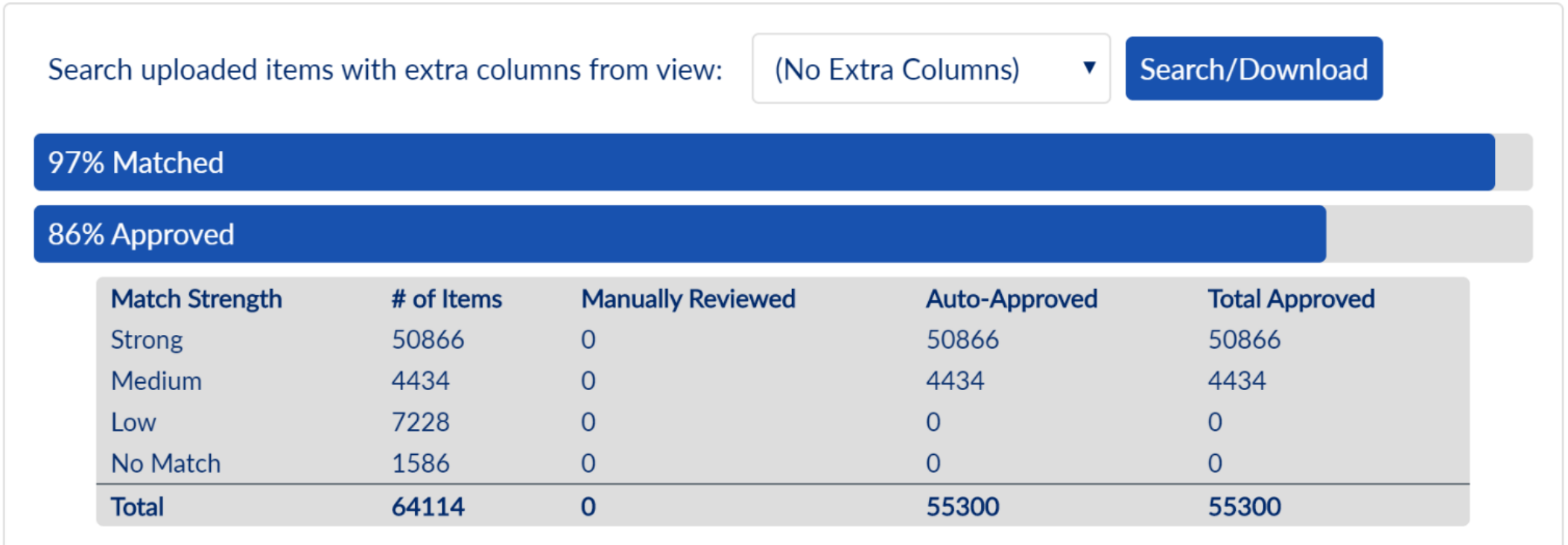
- identifies inaccuracies for each product set – highlights errors or inconsistencies with each product data set

- machine learning allows for identification of product data inaccuracies, automation

Consolidated Product Data Source: identifies integrity of data

- Upload excel/csv and have results in minutes
- Create custom data feeds to other systems

item_master.csv



Match Strength	# of Items	Manually Reviewed	Auto-Approved	Total Approved
Strong	50866	0	50866	50866
Medium	4434	0	4434	4434
Low	7228	0	0	0
No Match	1586	0	0	0
Total	**64114**	**0**	**55300**	**55300**

Engaging users with value-add solutions

Opportunity Comparisons

	Option A	Option B
Line Number	-	**461335 ($17,885.00 savings)**
Description	AZURE S DR MRI SURESCAN PACEMAKER IMPLANTABLE DUAL-CHAMBER RATE-RESPONSIVE STERILE IMPLANT CONDITIONAL SINGLE-USE IPG W3DR01 WL USA	ESSENTIO MRI EL DR PACEMAKER IMPLANTABLE DUAL-CHAMBER RATE-RESPONSIVE STERILE IMPLANT CONDITIONAL SINGLE-USE
Distribution	In Commercial Distribution	In Commercial Distribution
Department	CARDIOVASCULAR	CARDIOVASCULAR
GMDN	Dual-chamber implantable pacemaker, rate-responsive	Dual-chamber implantable pacemaker, rate-responsive
FDA Code	LWP	LWP
UNSPSC	42203501	42203501
HCPCS	C1785	C1785
Company Name	medtronic	boston scientific
Catalog Number	W3DR01	L131
Total Active Recalls	16	9
Total Recalls	20	11
Total Adverse Events	77	69
Single Use	✔	✔
Labeled NRL	✘	✘
Labeled No NRL	✘	✘
Instrument	✘	✘
Implant	✔	✔
Device Sterile	✔	✔
Sterilize Before Use	✘	✘

We can change healthcare, but not alone

Errors Corrected	GUDID	Symmetric
Catalog Number Populated	58%	99%
Labelers Consolidated (M&A)	5,700	4,900
Device Descriptions Populated	80%	100%
Device Sizes Populated	27%	60%
Premarket Numbers Populated	45%	58%

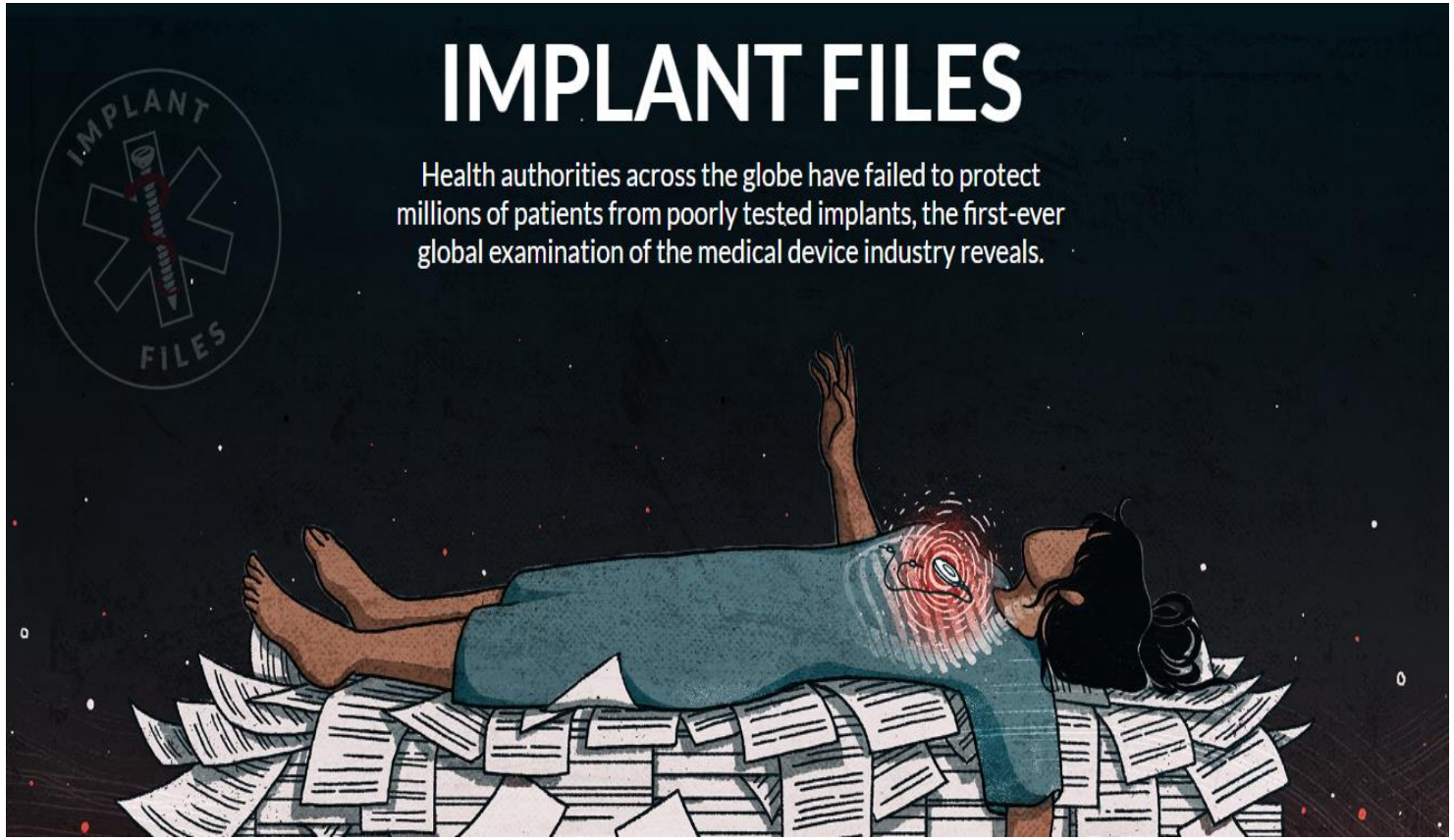
"It is my firm belief that many healthcare organizations would find Symmetric's software and expertise extremely valuable. The collection of information & dashboards they have built can dramatically impact an organization's efficiencies and bottom line."

-Customer: Joseph D'Amore, Manager MDM BMC

Clinically Integrated Supply Outcomes Model (CISOM)

Supply chain infrastructure to support system improvement and personalized care.

Patient Harm



International Consortium of Journalists, https://www.icij.org/investigations/implant-files

83,000

deaths linked to Medical Devices from 2008 to 2017 (adverse event reports)

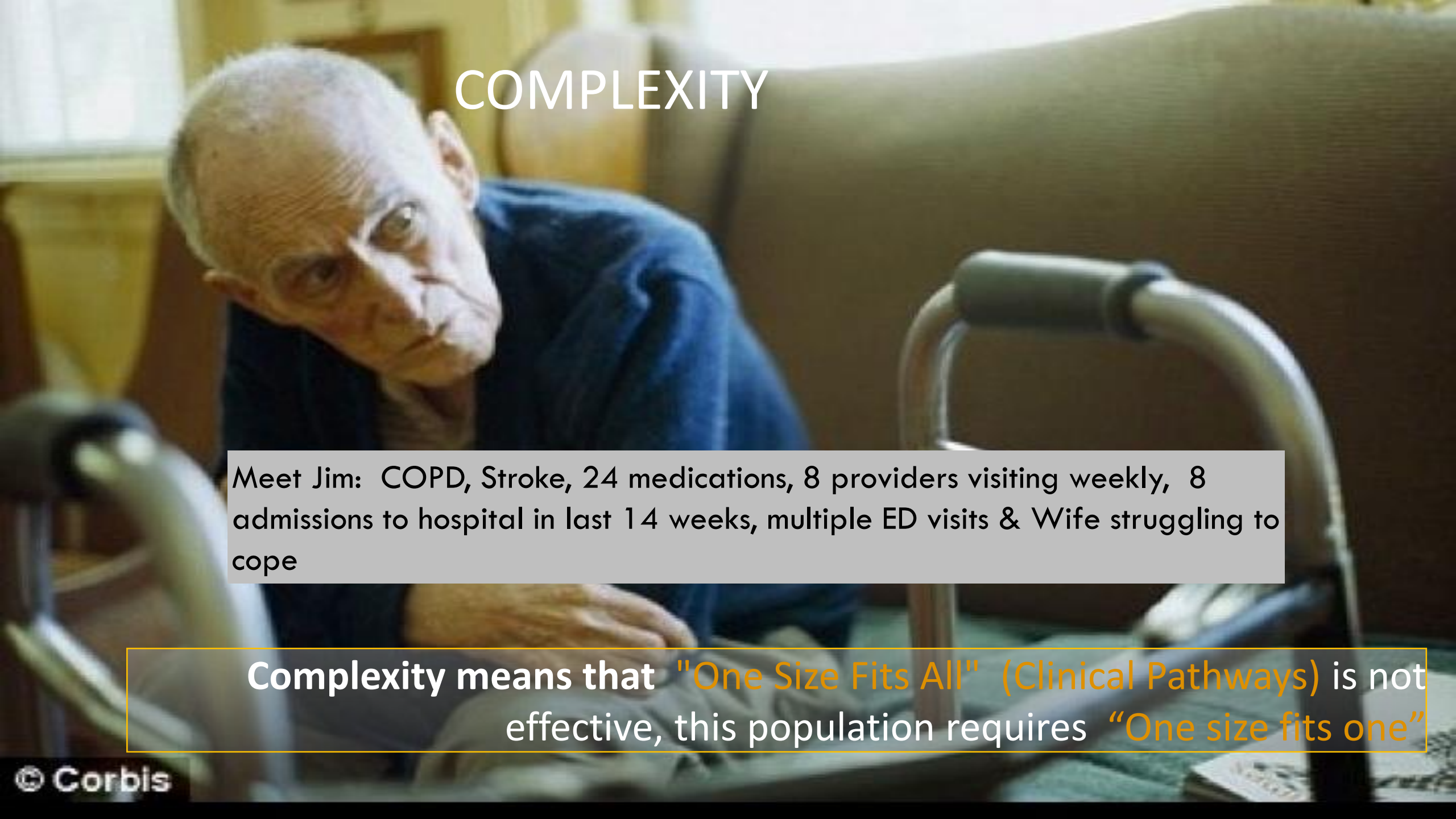
Patient harm is the 14th leading cause of global disease burden, comparable to Tuberculosis and Malaria (WHO, 2018)

In hospital, 1 in every 10 patients is harmed (WHO, 2018)

Significant Pressure to Find Value at the System Level to Achieve Sustainability

HIMSS Analytics

COMPLEXITY



Meet Jim: COPD, Stroke, 24 medications, 8 providers visiting weekly, 8 admissions to hospital in last 14 weeks, multiple ED visits & Wife struggling to cope

Complexity means that "One Size Fits All" (Clinical Pathways) is not effective, this population requires "One size fits one"

Drive Towards Value-Based Healthcare

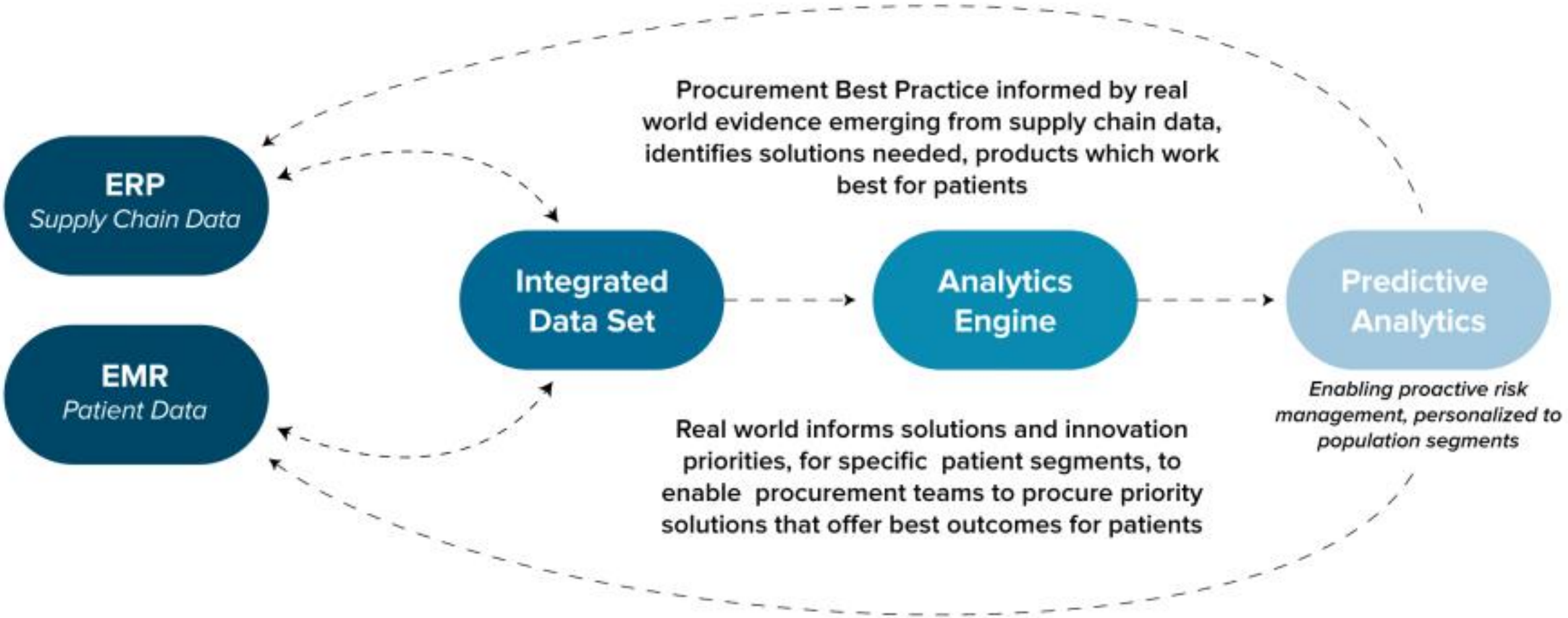
$$\text{Value} = \frac{\text{Health outcomes that matter to patients}}{\text{Cost of delivering these outcomes}}$$

"Setting the goal as cost containment, rather than value improvement, has been devastating to health care reform efforts. Cost reduction, without regard to the outcomes achieved, is dangerous and self-defeating, leading to false "savings" and potentially limiting effective care." *(Porter, 2010)*

Emerging Digital Health Systems

FEATURES	TODAY	TOMORROW
PAYMENT	Fee for Service	Outcomes
INCENTIVES	Volume	Value
FOCUS	Disease management	Health and Wellness
PROVIDER ROLE	Illness Episodes, transactional	Consumer Self Management, Provider as Care Partner
INFORMATION/DATA	Retrospective, clinical trial pathways	Predictive, proactive management of risk

Clinically Integrated Supply Chain Enables Transparency of Real World Data and Evidence of Value & Performance



Key Focus Areas of H-SIMM

Automation: automation of data capture for products, care processes, clinician teams, procurement, traceability of products and supplies.

Integration: clinical integration of supply chain expertise in clinical programs, automated data captured at point of care

Data>Information>Knowledge: data captured at point of care, uploaded and translated into knowledge of forecast purchasing, productivity, to identify value, safety at point of care.

Leadership: C-suite leaders view supply chain infrastructure as a strategic asset for the organization, mobilize teams to advance supply chain strategy.

Automation of Clinical Environments

- **Point of Care Capture of Data – relies on adoption of global standards**
- **Automated inventory management via EDI** exchange with vendors
- **Automated recall and expiry alerts to clinicians**
- **Online adverse event reporting and** analytics

Integration of Supply Chain Expertise into Clinician Teams

- **Supply Chain team mobilizes digital tools, data, analytics for Clinician leaders and Program leaders to inform decisions**
  - **Procurement decisions informed by evidence of outcomes**
  - **Reduced Variation in Care to drive standardization**
  - **Tracking quality outcomes: errors, never events**
  - **Standardization to reduce variation in care**
  - **Creates Real World Evidence of Outcomes and Value**

Data Analytics: Transform data into Knowledge and Real World Evidence

Proactive alerts at point of care

- Eg. Risk of sepsis, guard against "never events"

- **Proactive and predictive management of risk**
- **Automated adverse event tracking -** accessible to patients, clinician teams
- **Enables population segmentation based on outcomes and value**

Leadership and Governance:

- **C-Suite:** view **supply chain as a strategic asset** that "brings the entire organization together
- **Transparency** >> Accountability for Outcomes
- **Patient access to data and tools**, report outcomes, connectivity with provider teams
- **Clinicians lead Quality** and Safety initiatives, outcomes tracked and reported publicly

Impact of Supply Chain Transformation in Global Health Systems

Alberta Health Services (AHS), Canada

- Integration of supply chain processes into clinical programs across the entire province
- Integration into patient information system at point of care planned 2019
- Online Adverse event reporting system and performance dashboard

7:1 ROI to date | $301,438,786 in savings over 7 years in inventory only

National Health Services, England (NHS), United Kingdom

- Implemented supply chain infrastructure in six NHS trusts' specialty programs, traceability of patients, providers, locations, products and outcomes
- By 2021, implementation planned for all 148 trusts is expected to generate £1 billion in savings (£30 million/month)

4:1 expected by year 3 from inventory savings | £1,034,000,000 savings projected by year 7 (£30M/mon. all Trusts) | Equivalent of 16 FTE's in labor savings/ Trust

Mercy Health, United States

- Integration of supply chain best practices into Perioperative program in 3 of 45 hospitals
- Automated perioperative environments with point of care scanning – integrated supply chain team and clinician teams

$1 billion in savings as a direct outcome of optimizing and transforming supply chain processes, most savings due to inventory management | 29.5% decline in labor costs and 33% decline in supply costs

SCANH
Supply Chain Advancement Network in Health

NCE RCE
Networks of Centres of Excellence of Canada | Réseaux de centres d'excellence du Canada

SCANH2020 will take place next Fall.
Visit www.scanhealth.ca for updates.

Contact Us

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Find us online at: www.scanhealth.ca

Follow us on Twitter: @SCAN_Health

Like us on Facebook: Supply Chain Advancement Network in Health

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Thank you!

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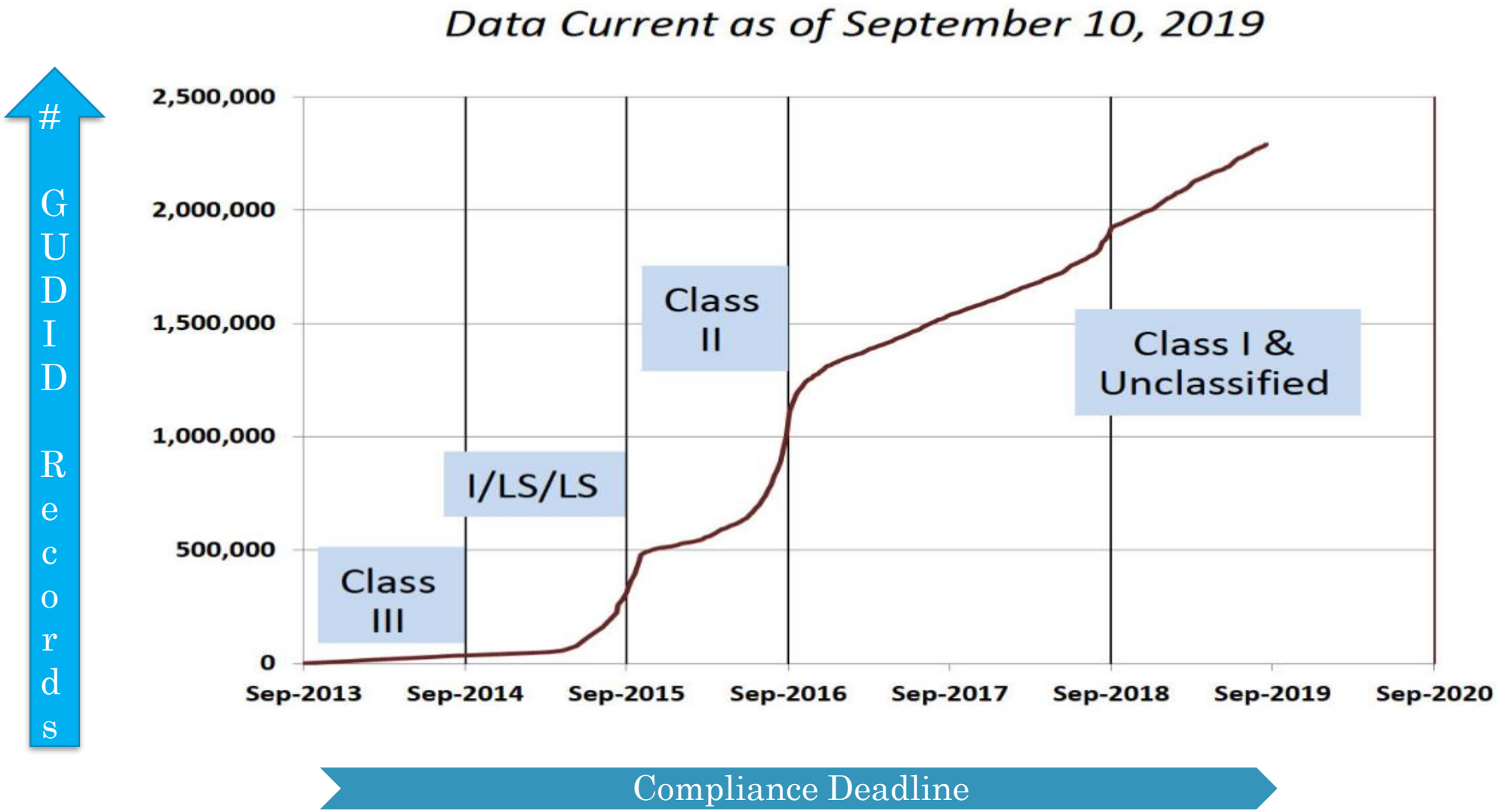
FDA UDI Update

Behnaz Minaei

October 2019

GUDID Records and submission compliance date



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US FDA Compliance Dates

Compliance Date	Must bear a UDI and Submit data to GUDID	Direct Marking (for certain intended uses)
✓ Sep 24, 2014	Class III devices Devices licensed under the PHS Act	
✓ Sep 24, 2015	Implantable, life-supporting and life-sustaining (I/LS/LS) devices	LS/LS devices
✓ Sep 24, 2016	Class II devices	Class III devices and devices licensed under the PHS Act
Sep 24, 2018	Class I devices Unclassified devices	Class II devices
Sep 24, 2020	Class I devices Unclassified devices	Class I devices Unclassified devices
Sep 24, 2022	**Extended via ED guidance**	Class I devices Unclassified devices

FDA Progress

- GUDID Updates:
  - 2.3 million records in GUDID
  - Grace Period changed from 30 days to 7 days
  - Enhancements to allow for submission of CDER approved FDA Premarket Submission Numbers
  - DQ emails for several issues
- FDA Issued UDI Citation

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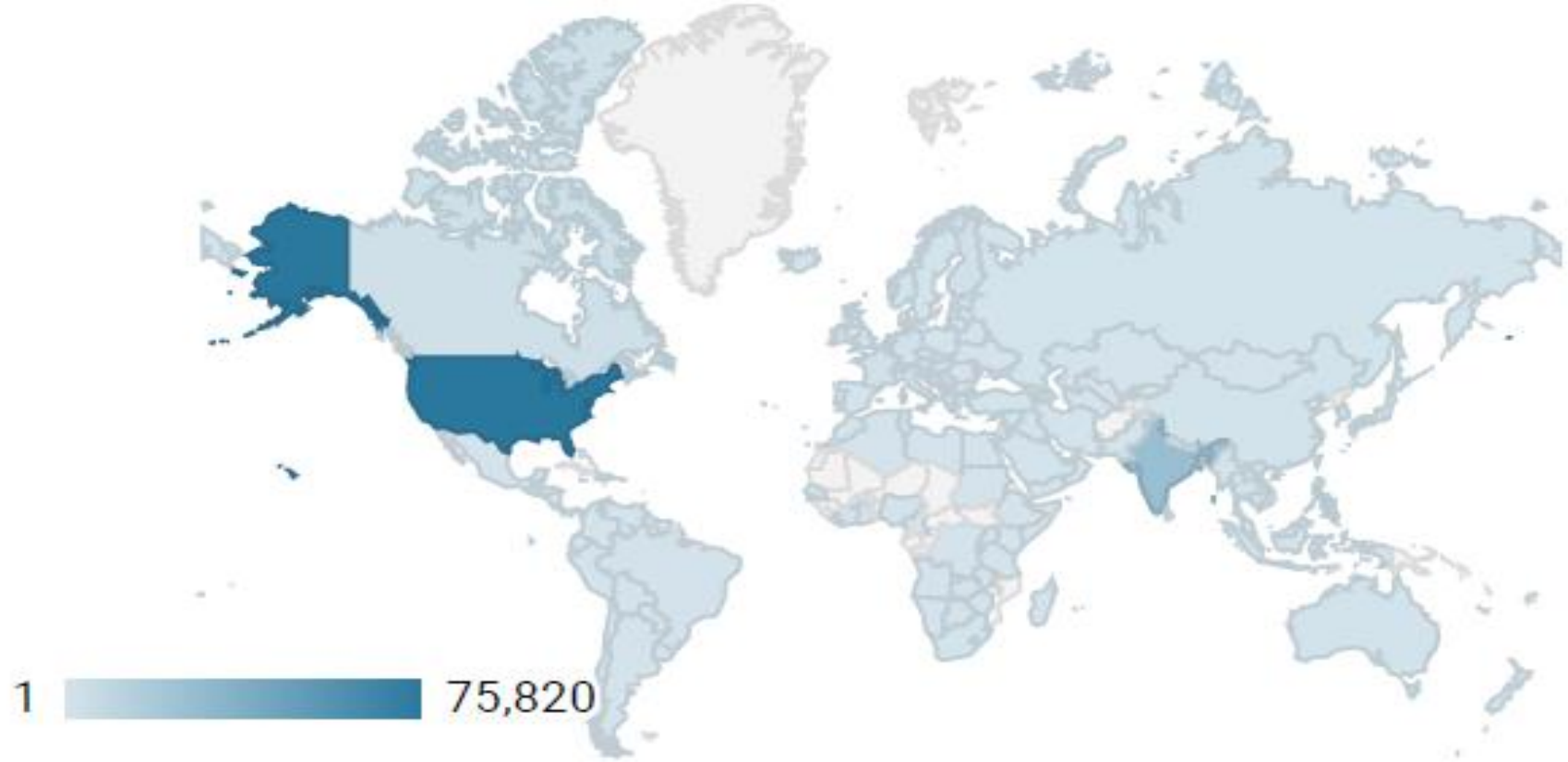
AccessGUDID User Engagement



International Medical Device Regulatory Forum

- IMDRF/UDI WG/N48 FINAL: 2019

  Unique Device Identification system (UDI system) Application Guide - PDF (3.53Mb)

- IMDRF/UDI WG/N54 – Use of UDI in Healthcare

  System requirements related to use of UDI in healthcare including selected use cases - PDF (306kb)

- IMDRF/UDI WG/N53 – Comparison of Data Elements across IMDRF jurisdictions

  Annex - Use of UDI Data Elements across different IMDRF Jurisdictions - XLSX (391kb)

IMDRF – UDI/N48

- Guiding principles for UDI system design and operations
- Content, Structure and representation of UDI
  - Consideration on Barcode Reader
- Application of UDI to packaging levels
- The Unique Device Identification Database (UDID)
- UDI Format and Structure When Entered into Forms, Databases, Registries, etc.
- Establishing Responsibility for Creating and Maintaining a UDI System
- General Considerations to Facilitate an effective UDI Implementation
- Special cases

IMDRF – UDI/N54 -Recording Unique Device Identifiers in Electronic Health Sources

General System Requirements for Recording the UDI

- The UDI Carrier (Automated Identification for Data Capture (AIDC) and human readable interpretation (HRI) representation of the UDI) shall be on the label or on the device itself and on all higher levels of device packaging. The following are recommended general system requirements to record the UDI available at the point of care and transmit the UDI across health systems:
- The system should be able to capture the data in the UDI Carrier. The system should be able to parse the UDI into its device identifier (UDI-DI) and production identifiers (UDI-PIs) (i.e., lot or batch, serial number, expiration date, manufacturing date, distinct identification code) to identify a device as part of device use. If the level of device identification detail required is limited to the model/version of the device and not the specific product, then only the UDI-DI should be recorded.
- The system should be able to capture all formats of the UDI as established by accredited issuing agencies/entities. See issuing agency/entity format descriptions (see Appendix A in UDI Application Guide Document)
- The system should be able to capture and save the UDI, the UDI-DI and all the UDI-PIs in distinct fields. This requirement is applicable to both electronic capture and exchange as well as for paper forms collecting device data.
- The system should be able use the UDI-DI as a real-time look-up to the appropriate UDID, verifying that the UDI-DI exists in the local UDID and/or in the UDIDs of other jurisdictions.

MDEPINET - ABSTRACT MODEL FOR COLLECTING WOMEN'S HEALTH CRN DATA

Advance the Coordinated Registry Networks (CRNs) capacity for Patient-Centered Outcomes Research (PCOR) use in 12 clinical areas through their development in 7 areas (attributes): patient engagement, unique device identification, data quality, efficiency, governance, sustainability and fitness for use during the total product life cycle (TPLC).

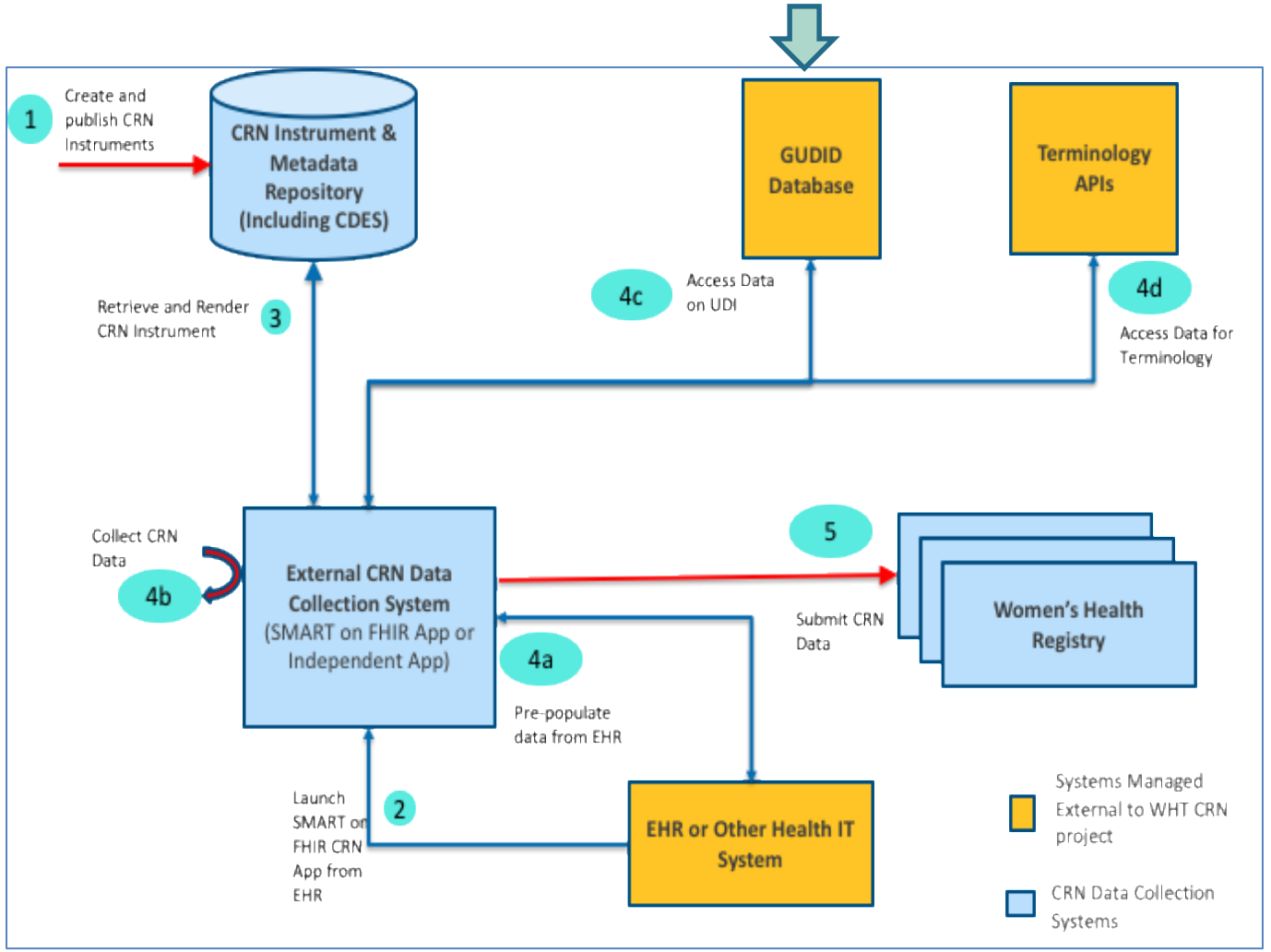
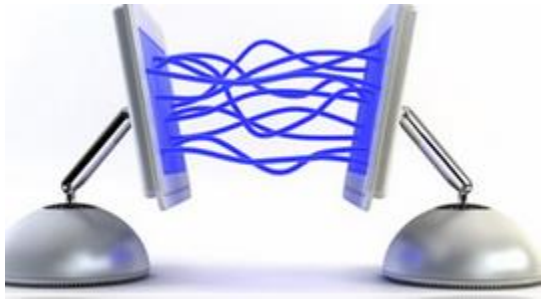


Figure 1. The abstract model, actors and the data flow for WHT CRN data collection.

UDI IN CLAIMS (X12)

- X12 published the revised 7030 version of the claims guides on Oct 15 for a 45 day comment period. The DI reporting remains in the guide. Estimated Q1 2024 implementation of the guides as a HIPAA requirement.
- X12 will also publish a 7030 version of the 275 Attachment transaction for public comment with a 60 day comment period. This allows reporting of the full UDI. It is, at this point, not a HIPAA standard although a proposed rule for its adoption is expected sometime in the next 6 months.



Healthcare Data Exchanges – HL7

HL7 Artifact	2019			2020			2021		
	Jan	May	Sep	Jan	May	Sep	Jan	May	Sep
U.S. Core – Interoperability			STU R2			STU R3			TBD
FHIR Device Resource			N/A	Trial R2		Trial R3		TBD	
C-CDA Companion Guide			STU R2		STU R3				TBD
UDI Pattern Guide		N-R2	N/A	N/A	?Align w/FHIR 5	N/A	N/A	N/A	Align w/FHIR 6
Domain Analysis Model (DAM)		I-R3	N/A	I-R4			N-1		
FHIR Payer Exchange			STU R1		STU R2		NR1		

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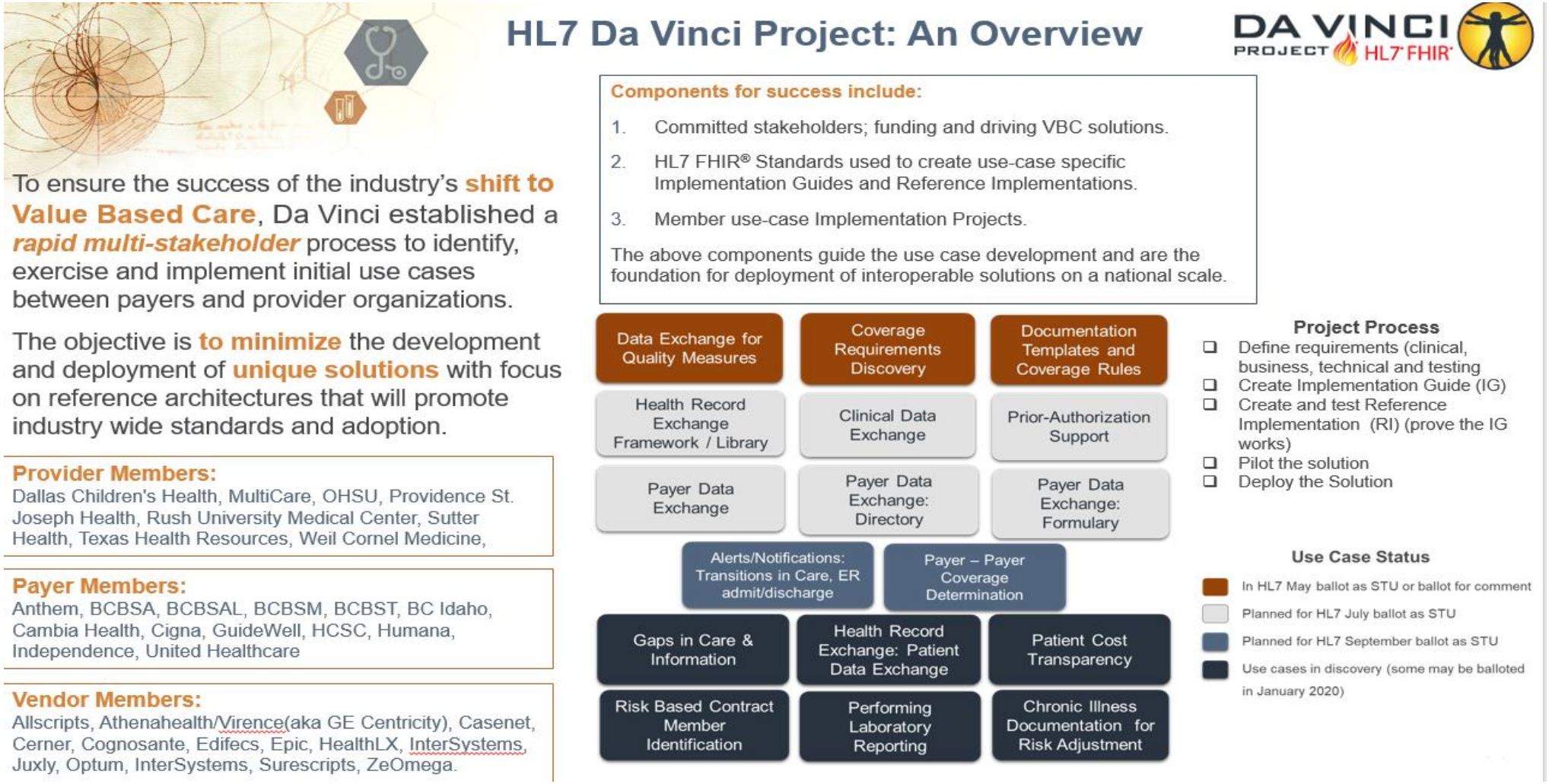
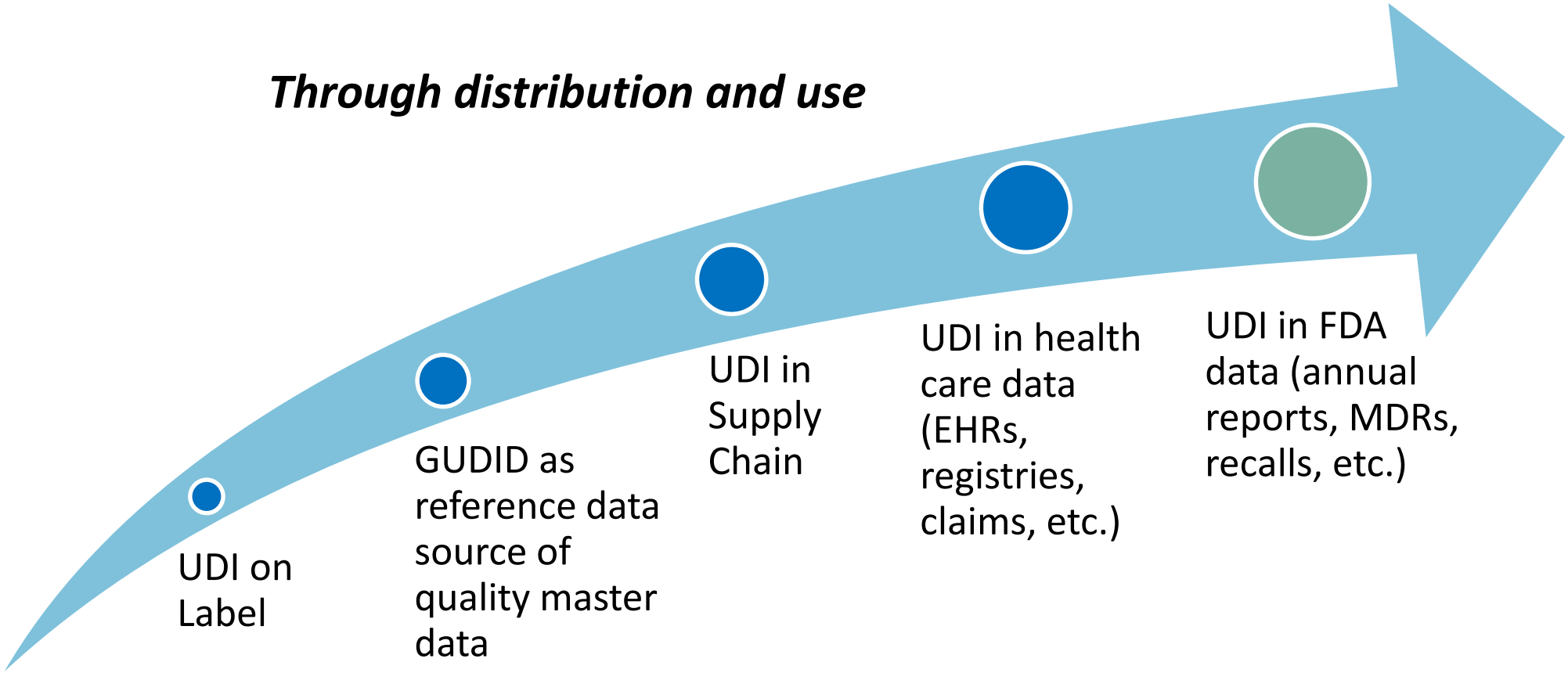
DAVINCCI


HL7 Da Vinci Project: An Overview
DA VINCI PROJECT HL7 FHIR
To ensure the success of the industry's shift to Value Based Care, Da Vinci established a rapid multi-stakeholder process to identify, exercise and implement initial use cases between payers and provider organizations.
The objective is to minimize the development and deployment of unique solutions with focus on reference architectures that will promote industry wide standards and adoption.
Provider Members:
Dallas Children's Health, MultiCare, OHSU, Providence St. Joseph Health, Rush University Medical Center, Sutter Health, Texas Health Resources, Weil Cornel Medicine,
Payer Members:
Anthem, BCBSA, BCBSAL, BCBSM, BCBST, BC Idaho, Cambia Health, Cigna, GuideWell, HCSC, Humana, Independence, United Healthcare
Vendor Members:
Allscripts, Athenahealth/Virence(aka GE Centricity), Casenet, Cerner, Cognosante, Edifecs, Epic, HealthLX, InterSystems, Juxly, Optum, InterSystems, Surescripts, ZeOmega.
Components for success include:
1. Committed stakeholders; funding and driving VBC solutions.
2. HL7 FHIR® Standards used to create use-case specific Implementation Guides and Reference Implementations.
3. Member use-case Implementation Projects.
The above components guide the use case development and are the foundation for deployment of interoperable solutions on a national scale.
Data Exchange for Quality Measures
Coverage Requirements Discovery
Documentation Templates and Coverage Rules
Health Record Exchange Framework / Library
Clinical Data Exchange
Prior-Authorization Support
Payer Data Exchange
Payer Data Exchange: Directory
Payer Data Exchange: Formulary
Alerts/Notifications: Transitions in Care, ER admit/discharge
Payer – Payer Coverage Determination
Gaps in Care & Information
Health Record Exchange: Patient Data Exchange
Patient Cost Transparency
Risk Based Contract Member Identification
Performing Laboratory Reporting
Chronic Illness Documentation for Risk Adjustment
Project Process
Define requirements (clinical, business, technical and testing
Create Implementation Guide (IG)
Create and test Reference Implementation (RI) (prove the IG works)
Pilot the solution
Deploy the Solution
Use Case Status
In HL7 May ballot as STU or ballot for comment
Planned for HL7 July ballot as STU
Planned for HL7 September ballot as STU
Use cases in discovery (some may be balloted in January 2020)

FDA Vision

Through distribution and use



Goals:

- **Global Adoption**
- **UDI in RWD/RWE (National Evaluation System)**

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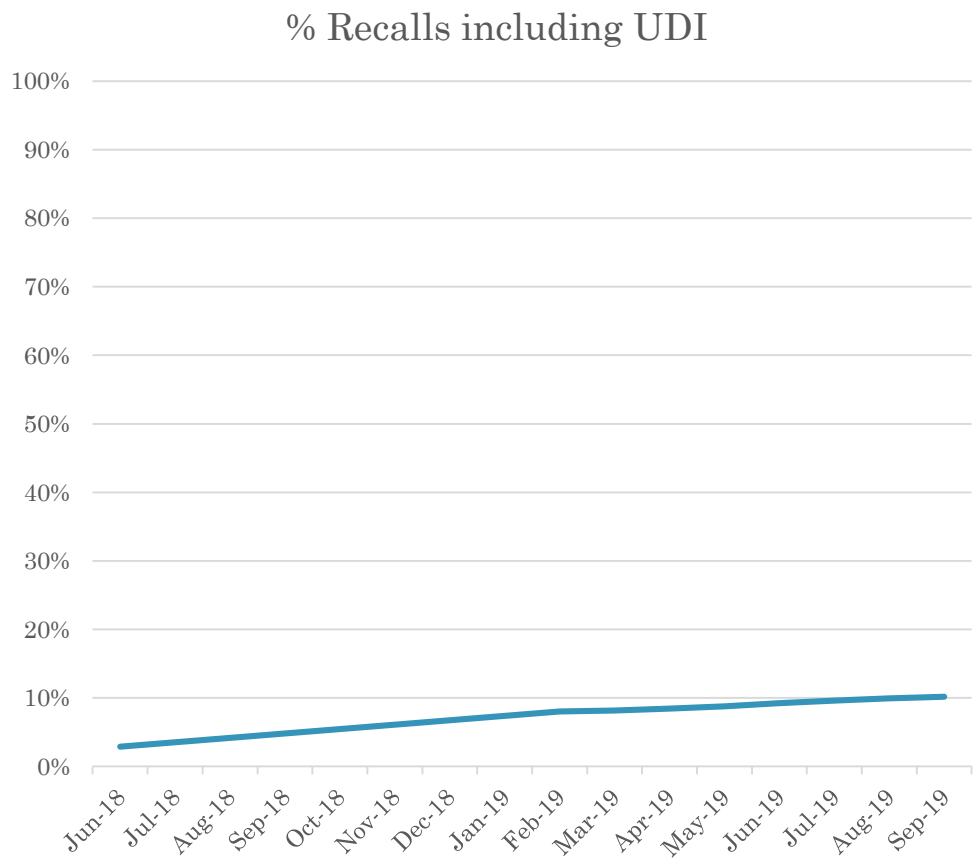
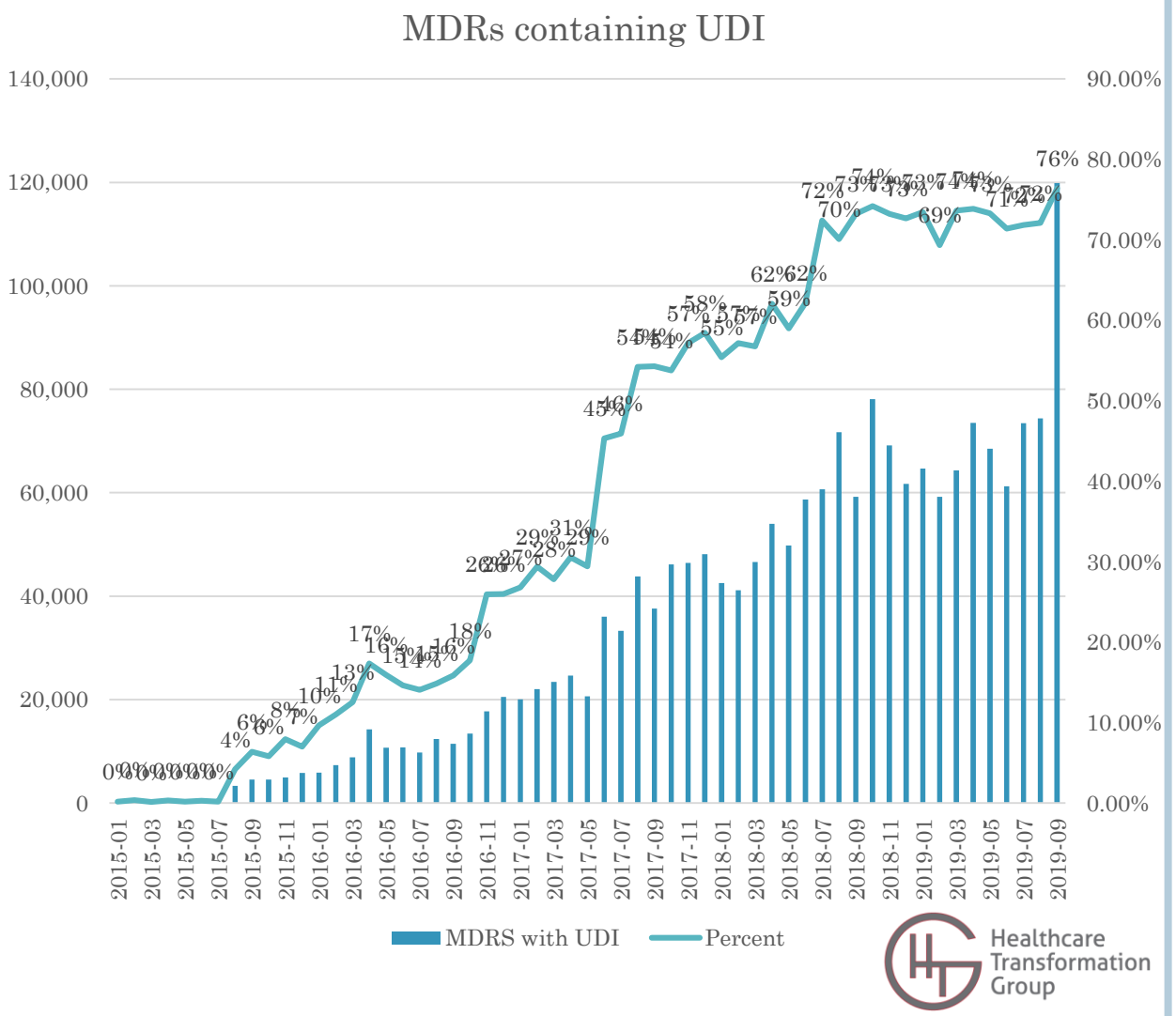
UDI in Recalls and Adverse Event





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Recall – Goldfish

Retail Consumers

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Pepperidge Farm® Announces Voluntary Recall of Four Varieties of Goldfish® Crackers

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release July 23, 2018

Contact

Consumers

Customer Service
800-679-1791

Media

Bethridge Toove
Bethridge_Toov
203-846-7136

Cell Phone Email Alert

From: Walmart.com Recalls <WMRecalls1@walmart.com>
Date: Wed, Jul 25, 2018 at 12:19 AM
Subject: Pepperidge Farm Recalls Varieties of Goldfish Crackers
Dear Valued Walmart Customer:

Pepperidge Farm has been notified by one of its ingredient suppliers that whey powder in a seasoning that is applied to some varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of caution, is voluntarily recalling select varieties of Goldfish crackers.

Pepperidge Farm has asked us to recall the products listed below with the corresponding Best by Dates. Our records reflect that you may have purchased one or more of the items listed below.

Description	UPC	Sell By Dates	Product Images
Pepperidge Farm® Goldfish® Flavor Blasted® Xtra Cheddar Crackers, 6.6 oz. Bag	1410008548	WO 11/25/18 WO 12/2/18 WO 12/9/18 WO 12/16/18 WO 1/20/19	

Recall - Comparison

Summary

Company Announcement Date: July 23, 2018

FDA Publish Date: July 24, 2018

Product Type: Food & Beverages
Snack Food Item
Food & Beverage Safety

Reason for Announcement: Potential to be contaminated with salmonella

Company Name: Pepperidge Farm

Brand Name: Goldfish

Product Descr

UPC Impacted	Description
1410008548	Pepperidge Farm ® Goldfish ® Flavor Blasted ® Xtra (
1410009658	Pepperidge Farm ® Goldfish ® Flavor Blasted ® Xtra (

New Search

Class 1 Device Recall

Date Initiated by Firm December 19, 2017

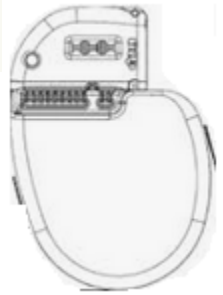
Date Posted February 01, 2018

Recall Status[1] Open[3], Classified

pacing (CRT-D devices).

Code Information

a. Product No. DTMB1D4: UDI 0064316954343(
RPJ201661H, RPJ202145H, RPJ
DTMB1Q1 UDI 0064316970578 (Serial No. RP
RPU201291H, RPU201293H, RP
RPU201300H, RPU201301H, RPU201302H, RP
RPU201619H, RPU201621H, RPU201635H, RP
RPE219331H, RPE218183H), 0064316954338(
RPE209095H, RPE212027H) (EXPANSION: Ser



Other News

- UDI included in CMS and ONC Interoperability Regulation (CMS-9115-P)
  - The CMS Interoperability and Patient Access Proposed Rule introduces new policies that will expand access to health information and improve the seamless exchange of data in healthcare.
- FDA CDER – Future Format of NDC code
- **FDA's Technology Modernization Action Plan | FDA**

Thank You

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AHRMM LUC INITIATIVES

Nancy LeMaster,
Interim Director
AHRMM LUC

UNIQUE DEVICE IDENTIFIER (UDI) VISION:

- One, consistent unique device identifier that would allow a device to be tracked from the point of creation, across the supply chain, into a patient's health record and beyond.
- Improve patient safety by enhancing the product recall process and supporting research to determine the clinical effectiveness and outcomes related to specific devices
- Streamline and improve the efficiency of the health care supply chain.

Learning UDI Community

The FDA has identified the need to actively engage with a coordinated, action-oriented, and early adopter unique device identifier (UDI) community. To answer this call, AHRMM has organized the **Learning UDI Community (LUC).** Accelerating UDI adoption across the health care field is essential to meeting the call for Cost, Quality, and Outcomes, the Triple Aim, and evidence-based care.

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Goals and Objectives

- Identify issues which impact UDI adoption across the healthcare industry
- Use inclusive, cross-functional workgroups to develop recommended practices and associated resources that will remove obstacles and accelerate adoption
- Provide public access to this shared knowledge

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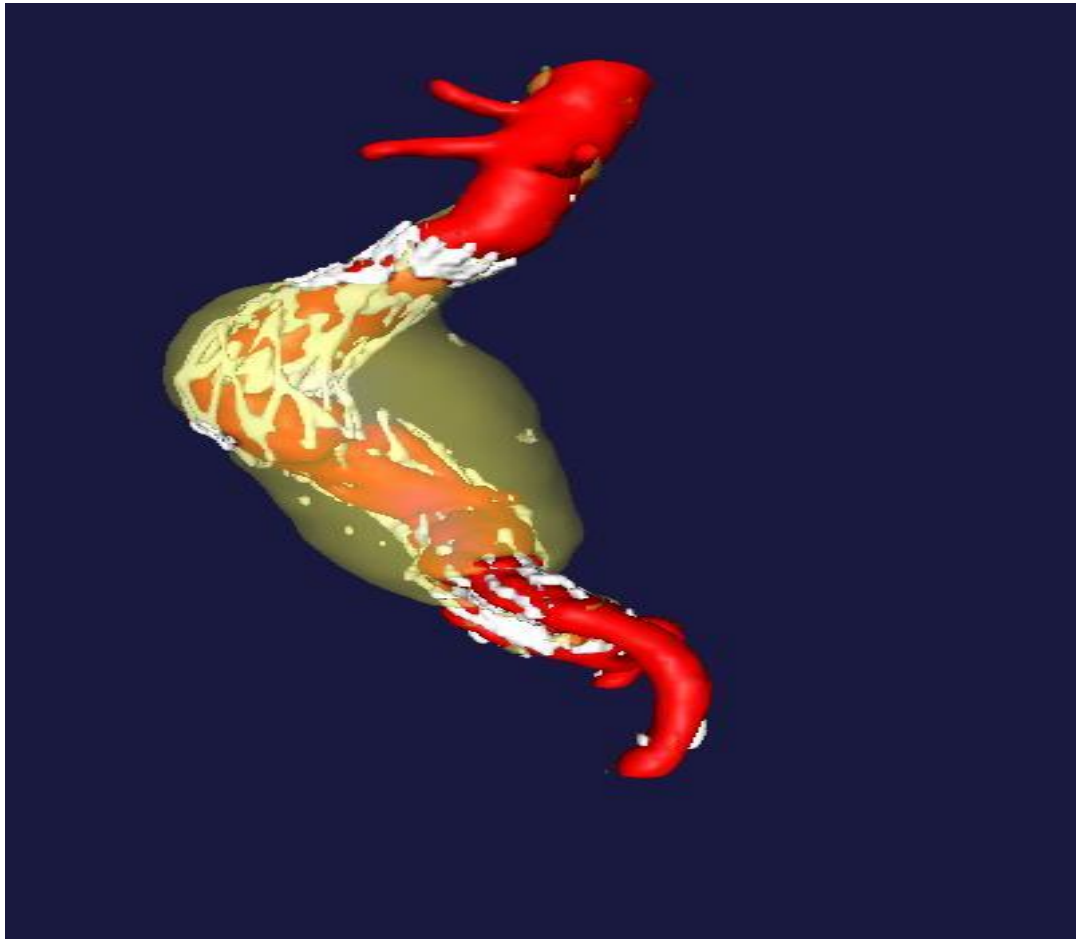
Why the UDI is Important



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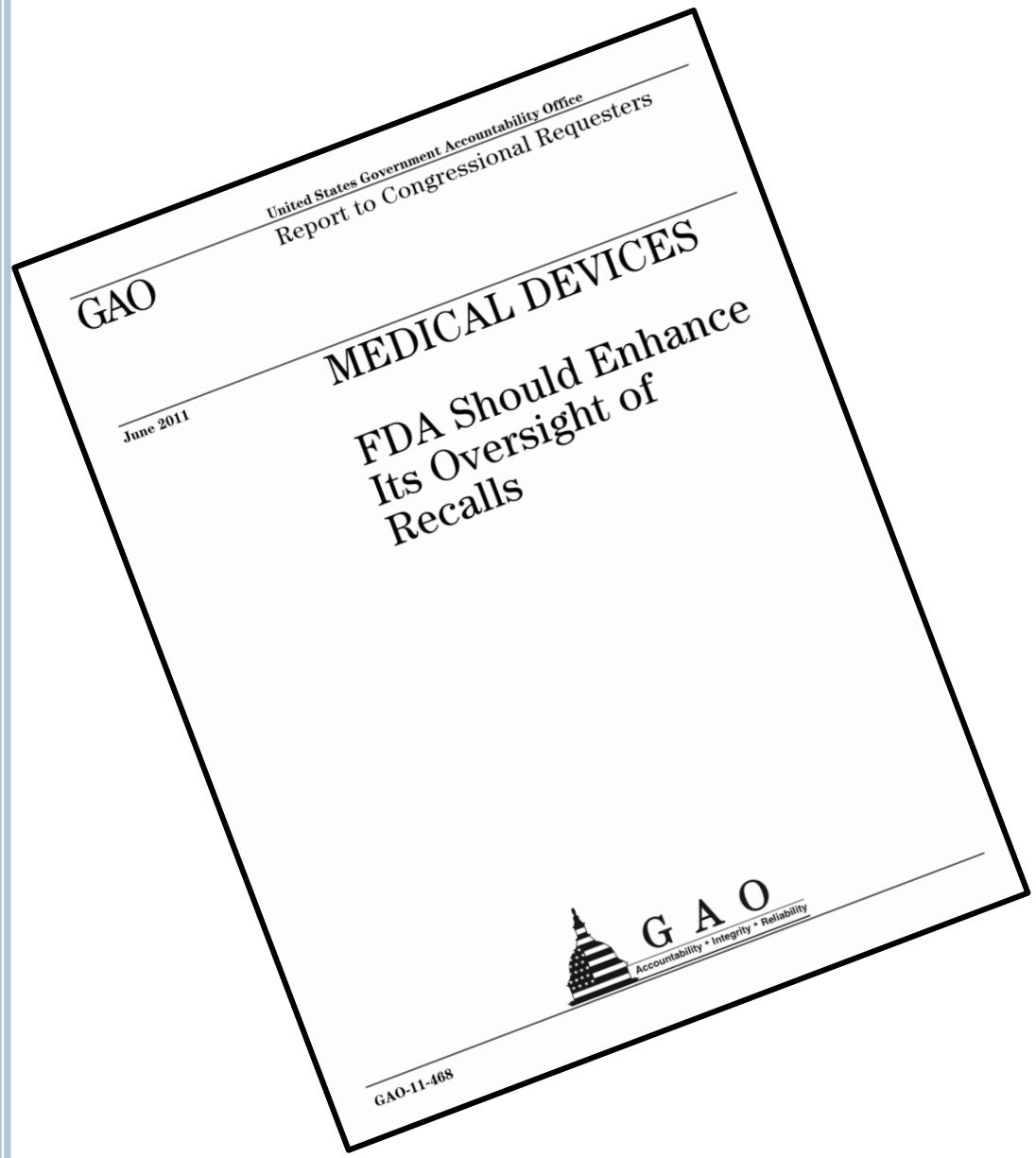
The recall challenge



"….firms initiated about 700 recalls per year. However we found that firms were unable to correct or remove all recalled devices thought subject to the highest risk or Class I recalls."

GAO showed that device firms do not remove all unsafe medical devices from the market because:

- The firm cannot locate all customers or devices
- Customers cannot locate the devices subject to recall.

In 53% of class I recalls, firms were unable to correct or remove all the faulty devices from the market.

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Manual Entry isn't feasible

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Challenges at the Point of Care

- Barcode Scanning
  - Multiple barcodes
  - Inadequate scanning technology
  - Non-compliant barcodes
  - Field inventory (pre-UDI stock)
  - Barcode only on the box and not on the device

Results taken from new AHRMM Learning UDI work group report on barcode scanning. to be published on the AHRMM LUC website soon.

www.ahrmm.org/luc

52%
of providers are NOT scanning UDI at Point of Care

64%
of providers don't know how to contact manufacturers with barcode or data issues.

86%
say a UDI icon or the word "UDI" next to the barcode would make it easier to identify at the point of care.

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Challenges at the point of care

- Multiple Device Identifiers
  - Manufacturers assign more than one UDI-DI to what providers consider the same medical device
  - Often done to manage internal distribution
  - Causes confusion among clinicians
  - Prevents providers from scanning at the point of care
- Inconsistent or inaccurate data in GUDID
- IT systems limitations (ability to hold and share data)

Read the entire report from the AHRMM Multiple Device Identifier Learning UDI work group at www.ahrmm.org/luc

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Recommended practices

Healthcare Providers

- Invite manufacturers on site to see the implications multiple barcodes and multiple device identifiers have on workflow and patient safety.

- Train staff on scanning techniques for dealing with multiple barcode packaging:
  - Scan the barcode adjacent to the human readable component of the UDI to identify the correct barcode. GS1 barcodes containing the UDI typically start with an (01) and HIBCC barcodes start with "+" followed by a letter (see Appendix for sample barcodes).
  - Have a formal process for inputting UDI information into EHR in the event of a barcode scanning failure. Make sure the process includes retaining the packaging of the failed barcode for diagnosis and follow up.

- Report errors in GUDID to manufacturers and FDA Help Desk.

Recommended practices

Manufacturers

- Minimize multiple barcodes on a point of use package by using 2D matrix barcodes or using qualifiers (application identifiers) to add information to a barcode without creating a separate barcode
- If multiple barcodes are used, add the ISO UDI symbol (available the end of 2019)
- Utilize qualifiers (application identifiers) whenever possible to minimize changes to UDI-DI
- Implement a formal and timely process for updating the GUDID
- Populate the contact field in the GUDID

Recommended practices

Software Application Providers

- Configure software to read all information (including hidden characters) contained within a barcode. Be able to parse and apply logic to all Application Identifiers, including the logic to ignore those AIs that are for internal manufacturing use only. Make sure the parsing program identifies delimiters (GS1 FNC1 Group Separator (GS)) after variable length fields.

- Software application provider systems must accommodate UDI-DIs for every level of packaging not just unit of purchase or unit of use. They also should provide functionality for providers to manage UDI-DI changes.

- Software application providers should collectively improve interoperability within and between systems to fully transact UDI.

Recently completed LUC initiatives

- Device Categorization:
  - Detailed analysis of GMDN and SNOMED CT
  - Recommended maximizing use of existing nomenclatures
  - Adding supplementary categorization resources that are use case dependent
- High Risk Implant:
  - Identified criteria to create an API for recommendations for AccessGUDID that would result in a list of high-risk implants
  - GMDN term code preferable to FDA Procode or combination of FDA Procode and GMDN Term code

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Collaborative problem solving

Problem Solving Via Collaborative Communities
The AHRMM Learning UDI Community

For more information,
visit the Learning UDI Community
at http://www.ahrmm.org/LUC

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Collaboration Session

(Four Corner Drill)

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Facility Tours

FMOLHS – Children's Hospital Supply Warehouse

Top Golf

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Welcome to Day 2
the 9th Annual HTG Summit

October 2019

Workday: Introduction for Healthcare Transformation Group

Keith Lohkamp, Sr. Director, Industry Strategy

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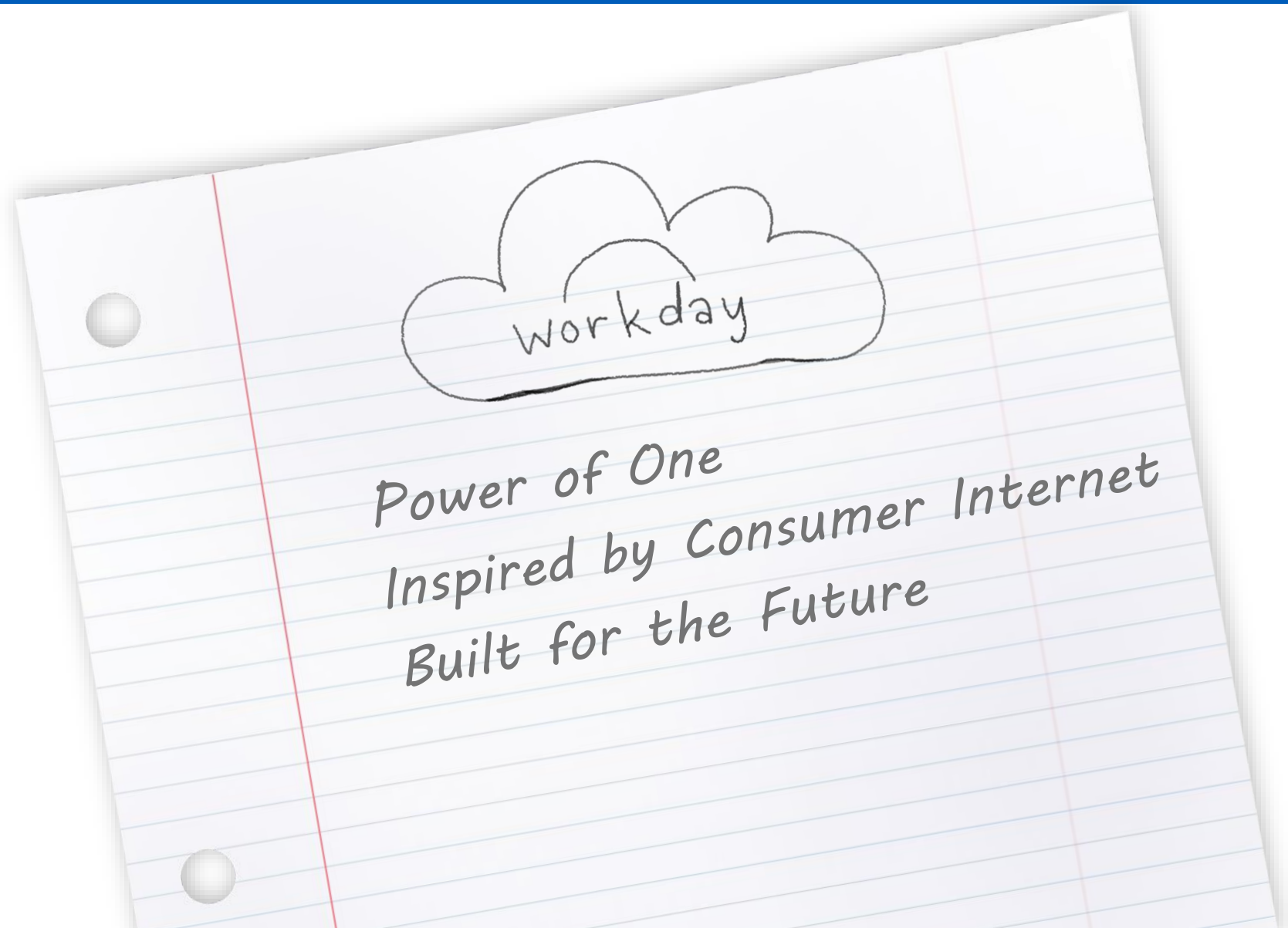
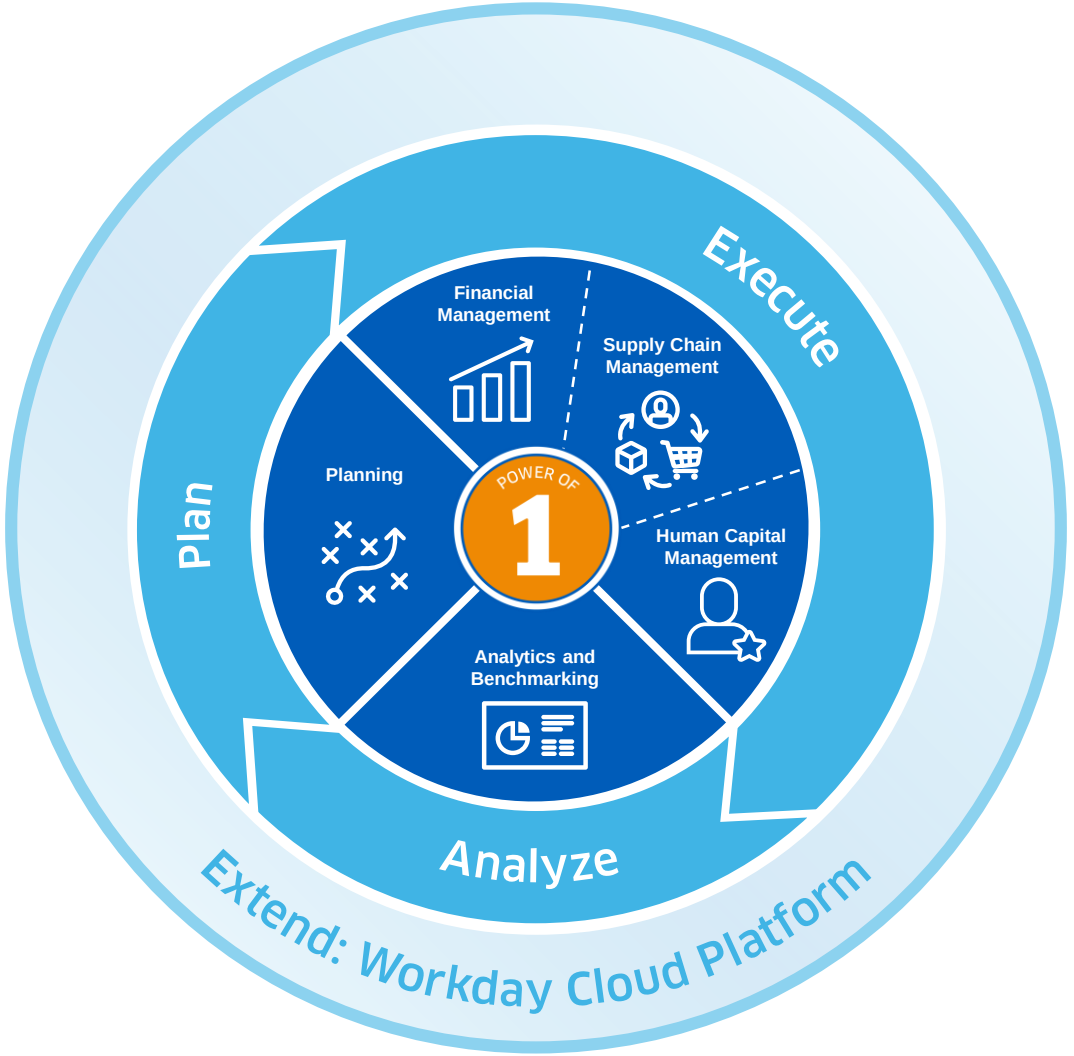
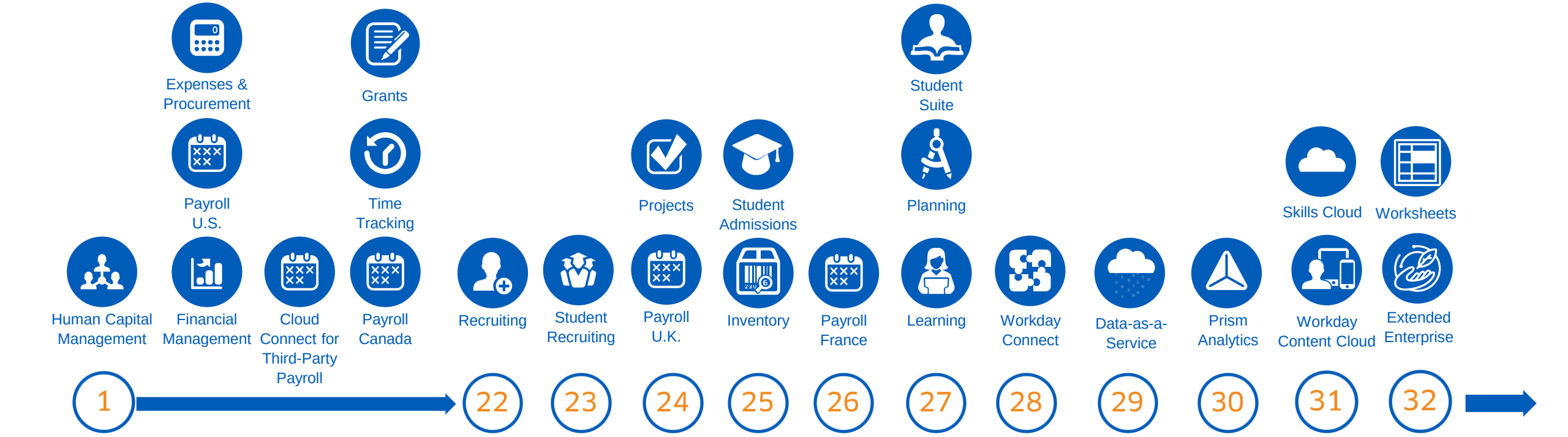
Workday Introduction



The Enterprise Cloud for Finance, Supply Chain and HR



Continuously Evolving



Meta Data | In Memory | Microservices | Integration Cloud | iPhone | Android | HDFS | Machine Learning | Analytics | Open Platform | Natural Language Processing

2006–2013 **2014** **2015** **2016** **2017** **2018** **2019**

One Technology Platform

Named a Leader by Industry Experts

Forbes
THE WORLD'S MOST INNOVATIVE COMPANIES 2018
Powered by THE INNOVATOR'S DNA

BEST IN KLAS
ENTERPRISE RESOURCE PLANNING (ERP)
2019

2019 Best in KLAS: Software / Services," January 2019.
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Magic Quadrant for Cloud Core Financial Management Suites for Midsize, Large, and Large Enterprises

Magic Quadrant for Cloud HCM Suites for Midmarket and Large Enterprises

constellation™ RESEARCH

Constellation ShortList™ Healthcare Enterprise Resource Planning, Q1 2019.
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KLAS
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TALENT MANAGEMENT
2019

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IDC | ANALYZE THE FUTURE

IDC MarketScape: Worldwide SaaS and Cloud-Enabled Finance and Accounting Applications 2017 Vendor Assessment I Sept 2017 I Doc #US42218017

IDC MarketScape: Worldwide SaaS and Cloud-Enabled Large Enterprise ERP Applications 2017 Vendor Assessment I Oct 2017 I Doc #US4221921

IDC MarketScape: Worldwide SaaS and Cloud-Enabled Midmarket ERP Applications 2017 Vendor Assessment I Sept 2017 I Doc #US42216017

Workday Healthcare Provider Customers

Full Cloud ERP Customers

Workday Supply Chain Management Solution

Spend Analysis & Planning	Sourcing and Vendor Management	Contract Management	Item Management	Procurement	Inventory
Spend and Supply Analytics	Supplier Master	Supplier Contracts	Item Master	Self-service Requisitioning	Inventory Site Setup
Capital Planning (Adaptive Insights)	RFP/RFQ Management	Supplier Catalogs	Item Attributes – Chargeable, Latex, etc.	Bill Only Requisitioning	Par including Kanban
Planning and Forecasting	Supplier Self-service Portal	Price Management	GS1/HIBCC Standards	Just in Time/LUM Replenishment	
Operational (Prism) Analytics	Supplier Registration	Contract Expiration and Spend Notifications	Catalog Management	Punchout	Perpetual Inventory
				Purchasing	Consignment
				Match and Pay	Delivery Capture
				Electronic Data Interchange (EDI)/XML	

One Platform


Business Process Framework


Security


Object Data Model

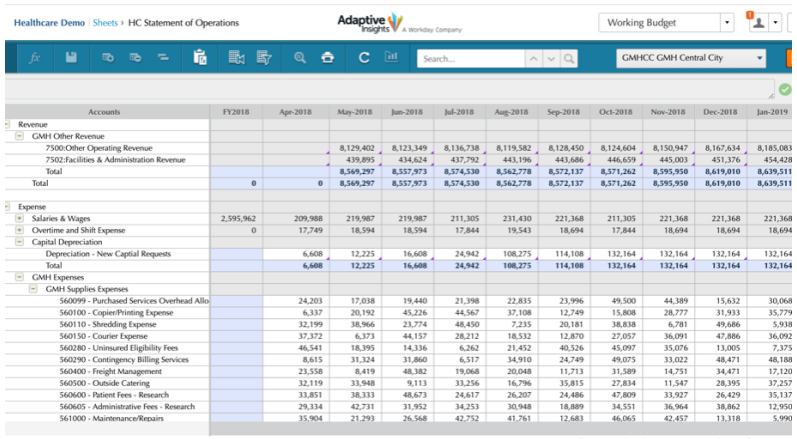

Machine Learning


Reporting and Analytics

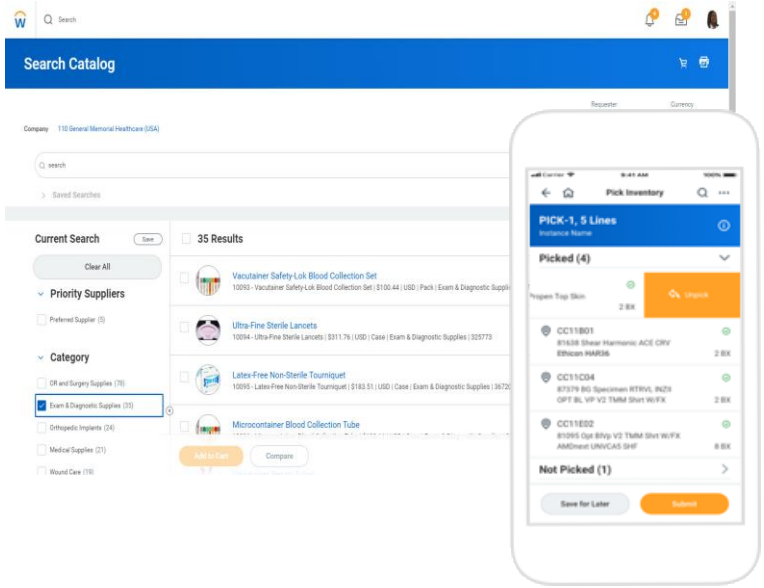

Integration Cloud

Workday Supply Chain Management Approach

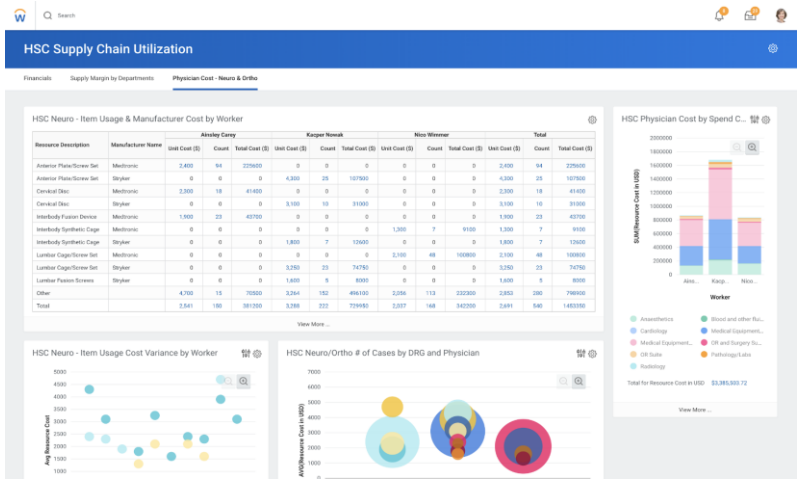
Active Business Planning



Efficient Supply Chain Execution



Contextual & Actionable Analytics



Imagine a Clinically Connected Supply Chain

Plan for fluctuations in volume to accommodate patient needs

Collaborate with clinicians and suppliers effectively

Deliver the right supplies at the right time

Understand impacts on patient outcomes and reimbursement

Support for Standards

Device Identification - GTIN

- Alternate item identifier per UOM on purchase or catalog items
- Searchable and displays
- Sent via EDI
- Scannable within mobile transactions, including concatenated barcodes
- Available in interfaces to EMR and POU
- UDI supported with lot / serial

Locations - GLN

- Define GLN for locations
- Transmit GLN via EDI

Product (GDSN) Attributes

- Tracked as either alternate item identifiers or item tags

UNSPSC

- Tracked against an item
- Mapping to Spend Category

Goals for Meeting

- Hear how initiatives are progressing
- Understand how Workday can help make it simpler to adopt standards
- Identify opportunities for specific collaboration

Built for the future.®

Thank you!

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Infor, Inc.

Jerry Rankin, Industry & Solution Strategy Director
Chris Wiekert, Sr. Product Manager

October 2019

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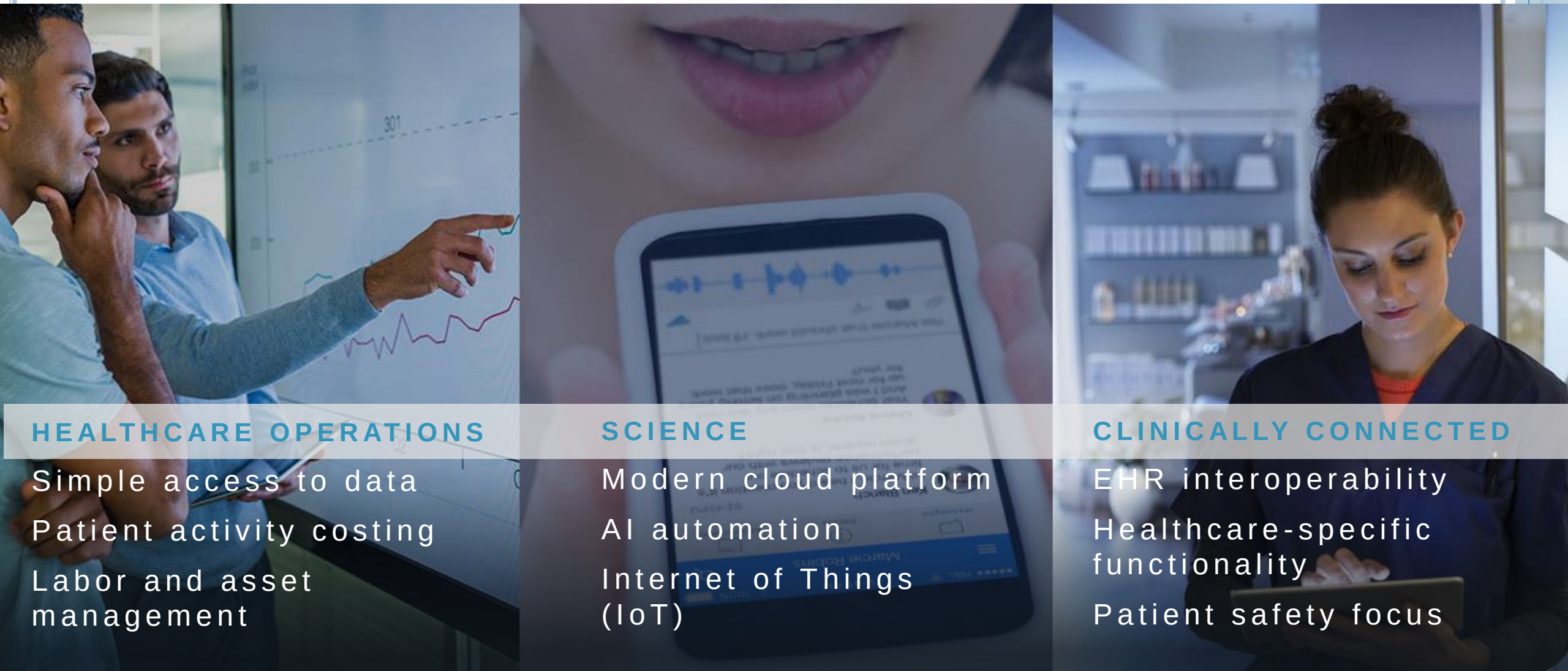
CONNECTING THE BUSINESS OF HEALTHCARE WITH THE MISSION OF HEALTHCARE

REDEFINING TRADITIONAL ERP IN HEALTHCARE

CLINICALLY CONNECTED HEALTHCARE OPERATIONS PLATFORM



HEALTHCARE OPERATIONS

- Simple access to data
- Patient activity costing
- Labor and asset management

SCIENCE

- Modern cloud platform
- AI automation
- Internet of Things (IoT)

CLINICALLY CONNECTED

- EHR interoperability
- Healthcare-specific functionality
- Patient safety focus

CLINICAL BRIDGE

Bridging Clinical and Business systems

CLINICAL BRIDGE ACTS AS THE UNIVERSAL ADAPTER BETWEEN EHR & ERP

Epic Cerner Others

- Item Load/Update
- Item Replenishment & Utilization
- ADT & Scheduling
- Patient Billing
- Patient Revenue
- Patient Refunds

HL7 Proprietary

infor Cloverleaf

Clinical Bridge

(translator)

Various Business Languages

Flat file
BOD
Web Services
Etc.

infor

- Contract Mgmt.
- Supply Chain
- Point of Use
- Financials


Mercy
Geisinger
MAYO CLINIC
FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM
HCA Healthcare
Yale NewHaven Health
CHRISTUS Health
PeaceHealth
Montefiore HEALTH SYSTEM
Penn Medicine
Confluence HEALTH
Lafayette General Health
NORTHOAKS Health System
Akron Children's Hospital
nch Northwest Community Healthcare
Valley MEDICAL CENTER
CONE HEALTH
PALOS HEALTH
ENLOE MEDICAL CENTER
SMH
Bermuda Hospitals Board
Northern Light
Parkland
ACTS Retirement-Life Communities
CHA Cambridge Health Alliance
BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.
RIVERSIDE HEALTHCARE
PREMIER HEALTH
FAITH REGIONAL HEALTH SERVICES
OneOncology
Froedtert & Medical College of Wisconsin
St Luke's
CONCORDIA PLAN SERVICES
Genesis
PALADIN HEALTHCARE
KINGSTON
DENVER HEALTH
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Infor and Data Standards

UDI (GS1, HIBCC) – capability since our version 9

Inbound Interface

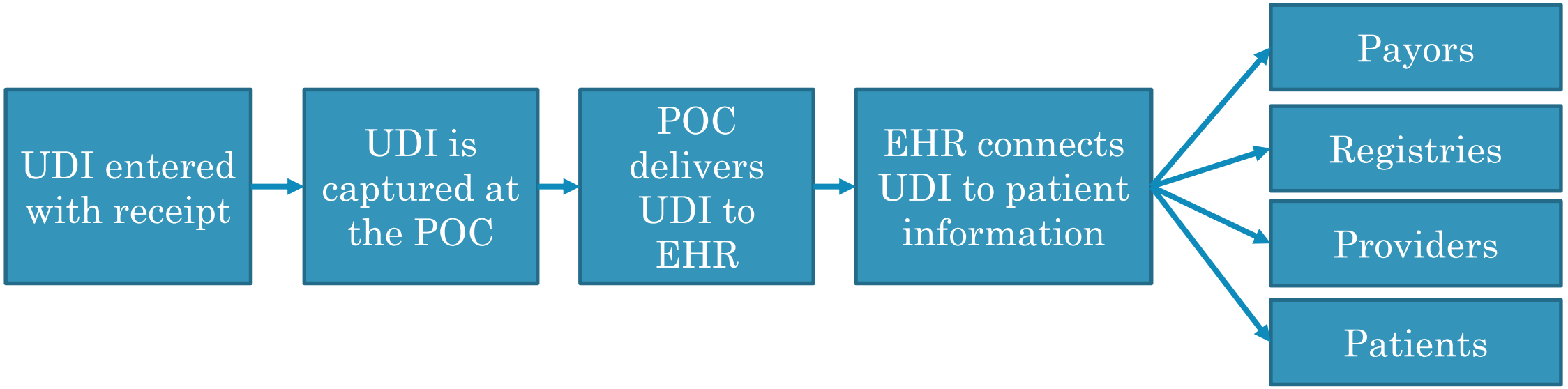
- **GDSN, manufacturers, data pools**

Outbound Interface

- **Clinical systems**
- **Other MMIS**

Infor and Data Standards

Procurement
Inventory Control
Contract Management
Mobile Supply Chain Management
Point of Use
EDI
Punchout
Recall Management



Data Standards Roadmap

- Increase areas of inbound data / API Gateway
- Capture on all relevant forms / automated workflows
- Sync with detail lot and serial tracking
- Improve reporting analytics
- Introduce AI and ML
- DSCSA
- Streamline/promote user adoption

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ORACLE

ORACLE

PeopleSoft GS1 Support

HTG 2019

Stephen Morgan
SRM/SCM Product Strategy Director

Bob Block
SRM Product Strategy Director

Oracle PeopleSoft
October, 2019

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PeopleSoft Healthcare Customers (w/Mobile Inventory Management)

- AdventHealth
- Alta Hospital Systems
- Anne Arundel Medical Center
- Asquam Community Health Collaborative
- Baptist Health South Florida
- BB Seguidade Participacoes, SA
- Beth Israel Deaconess Medical Center
- Baptist Health
- Beaumont Health
- Community Health Network
- Cape Cod Healthcare, Inc.
- Cheyenne Regional Medical Center
- Children's Hospital of Wisconsin
- Children's Hospital Colorado
- Children's National Medical Center
- Cincinnati Children's Hospital Medical Center
- Circle Health, Inc.
- City of Hope
- Dartmouth-Hitchcock Medical Center
- Emblem Health Services Co
- Fairfield Medical Center
- Fairview Health Services
- Great River Health Systems
- Hackensack University Medical Center
- Hartford Healthcare Corp
- Hospital Sisters Health System
- Houston Methodist Hospital
- Intermountain Health
- Kern County Hospital Authority
- Lucile Packard Children's Hospital
- Mary Hitchcock Memorial Hospital
- Massachusetts Eye & Ear Infirmary
- McLaren Healthcare Corporation
- Memorial Health Services
- Memorial Hospital at Gulfport
- Miami Children's Hospital
- Maimonides Medical Center
- Main Line Hospitals, Inc.
- NYC Health and Hospitals Corp
- Northwestern Memorial Hospital
- NYU Langone Medical Center
- National Jewish Health
- Nicklaus Children's Hospital
- Ohio Health
- Oklahoma Heart Hospital
- Pikeville Medical Center
- Presence Health
- Prospect Medical Holdings
- Queens Health Systems
- Quest Diagnostics, Inc.
- Regional Medical Center of Orangeburg
- Samaritan Health Services
- Springfield Clinic
- Saint Barnabas Corp
- San Antonio Regional Hospital
- Southcoast Health Systems, Inc.
- St. Elizabeth Healthcare
- Tampa General Hospital
- Tucson Medical Center
- Texas Health Resources
- The Guthrie Clinic
- Trinity Healthcare IS
- University of Virginia Med Center
- University of Iowa Hospitals and Clinics
- University of Texas SW Med Center
- Wake Forest University Baptist Med Ctr
- Yukon-Kuskokwin Health Corp
- Cedars Sinai Health Systems
- Hennepin Healthcare systems
- Lowell General Hospital
- Laboratory Corp of America
- Main Line Hospitals
- Sarasota Memorial Hospital
- Shands Teaching Hospitals & Clinics
- The Methodist Hospital System

PeopleSoft Healthcare Customers (w/ SRM and SCM)

- Anthem Health
- AmeriHealth Caritas Services
- Atria Senior Living
- BJC Health System
- Blue Cross/Blue Shield of Louisiana
- Blue Cross/Blue Shield Association
- Blue Cross/Blue Shield of Florida
- Brookdale Senior Living, Inc
- BMI Healthcare
- Capital Senior Living Corp
- CARE SSC Manila
- CARE USA
- CAREGROUP, Inc
- CENTENE Corp
- Children's Health System
- Children's of Minnesota
- Children's Hospital of Los Angeles
- CANCER CENTER OF WAKE FOREST UNIV
- Cambria Health Solutions, Inc
- Chesapeake General Hospital
- Correctional Health Services Corporation
- DELTA DENTAL PLAN OF MICHIGAN INC
- Drogaria Sao Paul SA
- Dubois Regional Medical Center
- ERLANGER MEDICAL CENTER
- East Jefferson General Hospital
- Encompass Health
- Erlanger Health Systems
- Estudios Clinicos DR. T.J. Oriard
- Fidelis Care New York
- First Nations Health Authority
- Grady Health Systems
- Great River Medical Center
- HEALTH FIRST INC
- HENRY FORD HEALTH SYSTEM
- Harris County Hospital District
- Health Management Systems
- HealthNow New York Inc.
- Healthspring, Inc.
- Highmark
- Horizon Blue Cross Blue Shield of NJ
- IHC HEALTH SERVICES INC
- INTEGRIS HEALTH
- Independence Blue Cross LLC
- Kaiser Foundation Hospitals
- LAHEY CLINIC BURLINGTON
- LEXINGTON MEDICAL CENTER
- LIFESPAN
- LSU Health Sciences Center
- Lab Corp of America
- Lahey Health
- Leids Universitair Medisch Centrum
- Logistics Health Inc
- London Health Sciences Centre
- Joint Commission on Accred of HCare Orgs
- Medica Sur S.A.B. de C.V.
- MetLife Services and Solutions, LLC
- NORTH MISSISSIPPI MEDICAL CENTER
- North Shore LIJ Health System
- Northwell Health, Inc.
- Optum Health & Technology Servicos Do Brasil
- Partners Healthcare
- Piedmont Healthcare – TE
- Pitsanuloke Medical Co Ltd
- Premera Blue Cross
- Presence Care Transformation Corp
- Prospect Medical Holdings, Inc.
- Rady Children's Hospital
- Sarasota County Public Hospital
- Sarasota Memorial Hospital
- SpecialityCare, Inc
- Texas Children's Hospital
- The Charlotte-Mecklenburg Hospital Authority
- The Hospital For Sick Children
- UNIV OF WISCONSIN HOSPITAL & CLINICS
- University of Pittsburgh Med Center
- UW HEALTH
- Vidant Health
- Wake Forest University Baptist Medical Ctr

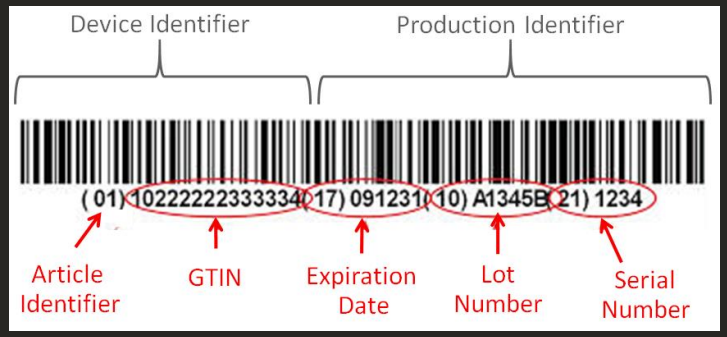
PeopleSoft Investment in supporting GS1

- Recognize that ‘Patient Safety’ is a top priority for our Healthcare Customers and implementing GS1 standards is part of that initiative
- Major investment in implementing GS1 standards across the PeopleSoft SCM and SRM products
- Looked at enhancements holistically across the whole of the PTP cycle
- Support GTIN parsing and transacting in GTIN as part of our Mobile Inventory product (par location replenishment, picking, receiving and putaway , delivery carts)
- Attendance at this summit to help validate enhancements and work with Healthcare Industry representatives on future requirements

PI 30 Deliverables

Delivered PI-30

- Extended definition to support additional formats (such as HIBC) using UPN type and UPN ID
- Ensures UPN / type is captured at time of transaction – before GTIN was display only but now stored on all of the PTP transactions
- Facilitates searching, transacting and storing UPN / UPN type on inbound and outbound transactions
- Requisition, Sourcing , Purchase Order, Contract, Receipt, Voucher and EDI transactions
- Ensures that UPN / UPN type is always in sync with Item / Manufacturer / Manufacturing Item ID/ UOM



PI 30 Detail

Delivered PI-30

- Requisition changed to store UPN / UPN type and ensure that any changes to UOM, Item will keep UPN in sync
- Requisition search changed to recognize if a specific UPN is entered and get the correct Item / UOM / Manufacturer info
- Contract setup now includes UPN and is part of the Contract selection process
- Online and batch PO sourcing ensures that UPN stays in sync based on UOM changes etc
- Purchase order will store UPN / type used at point of transaction and will keep UPN in sync if anything is changed on the PO

PI 30 Detail

Delivered PI-30

- Outbound and Inbound EDI transactions enhanced to include UPN and UPN type
- PO Documents including PO dispatch etc will display UPN
- PO Receipt provides visibility into UPN and UPN type
- UPN visibility added to Voucher
- UPN visibility added to eSettlements

Roadmap

Delivered PI-30

- UDI parsing including capture of lot number, lot expiration and serial number at receipt time (multiple fields , 2D barcodes ?)
- Ability to handle UPN changes as part of Inventory (need customer requirements in this area) – support one to many GTINs
- UPN as part of the matching process ?
- EPIC integration ?
- Recalls and Patient claims ?
- AI use cases

Thank you

Stephen Morgan

SRM/SCM Product Strategy Director

An Epic Update

Devin Bobulski

HTG Summit 2019

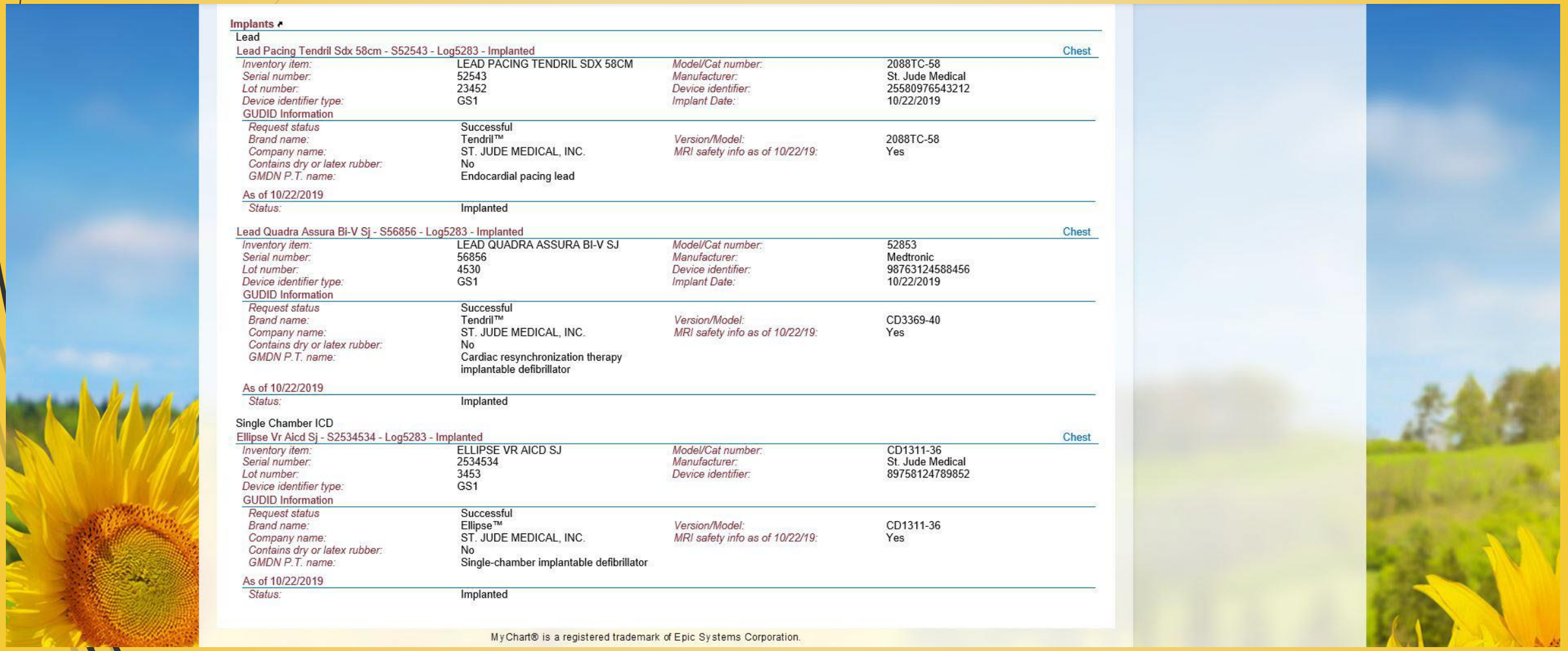
A Brief History of UDI in Epic

Support for Barcoding, UDI, and the GUDID

Where do we stand today?

Epic Community Adopting and Using UDI

Implants in MyChart



Implants

Lead

Lead Pacing Tendril Sdx 58cm - S52543 - Log5283 - Implanted — Chest

Inventory item:	LEAD PACING TENDRIL SDX 58CM	*Model/Cat number:*	2088TC-58
Serial number:	52543	*Manufacturer:*	St. Jude Medical
Lot number:	23452	*Device identifier:*	25580976543212
Device identifier type:	GS1	*Implant Date:*	10/22/2019

GUDID Information

Request status	Successful		
Brand name:	Tendril™	*Version/Model:*	2088TC-58
Company name:	ST. JUDE MEDICAL, INC.	*MRI safety info as of 10/22/19:*	Yes
Contains dry or latex rubber:	No		
GMDN P.T. name:	Endocardial pacing lead		

As of 10/22/2019

Status:	Implanted

Lead Quadra Assura Bi-V Sj - S56856 - Log5283 - Implanted — Chest

Inventory item:	LEAD QUADRA ASSURA BI-V SJ	*Model/Cat number:*	52853
Serial number:	56856	*Manufacturer:*	Medtronic
Lot number:	4530	*Device identifier:*	98763124588456
Device identifier type:	GS1	*Implant Date:*	10/22/2019

GUDID Information

Request status	Successful		
Brand name:	Tendril™	*Version/Model:*	CD3369-40
Company name:	ST. JUDE MEDICAL, INC.	*MRI safety info as of 10/22/19:*	Yes
Contains dry or latex rubber:	No		
GMDN P.T. name:	Cardiac resynchronization therapy implantable defibrillator		

As of 10/22/2019

Status:	Implanted

Single Chamber ICD

Ellipse Vr Aicd Sj - S2534534 - Log5283 - Implanted — Chest

Inventory item:	ELLIPSE VR AICD SJ	*Model/Cat number:*	CD1311-36
Serial number:	2534534	*Manufacturer:*	St. Jude Medical
Lot number:	3453	*Device identifier:*	89758124789852
Device identifier type:	GS1		

GUDID Information

Request status	Successful		
Brand name:	Ellipse™	*Version/Model:*	CD1311-36
Company name:	ST. JUDE MEDICAL, INC.	*MRI safety info as of 10/22/19:*	Yes
Contains dry or latex rubber:	No		
GMDN P.T. name:	Single-chamber implantable defibrillator		

As of 10/22/2019

Status:	Implanted

Moving the (UDI) Needle

Improving UDI Capture and Operational Success

Some observations

Challenges, Opportunities, and Ideas

Questions

Devin@epic.com

GDSN and Item Synchronization Update in Healthcare

Jeff Holzman,
Director, Industry Advancement
1WorldSync
jholzman@1worldsync.com **+1-973-220-0046**
Revision: 10/22/2019 8:54 AM

GDSN and Item Synchronization Update in Healthcare

WHAT IS THE GDSN?

WORLD SYNC

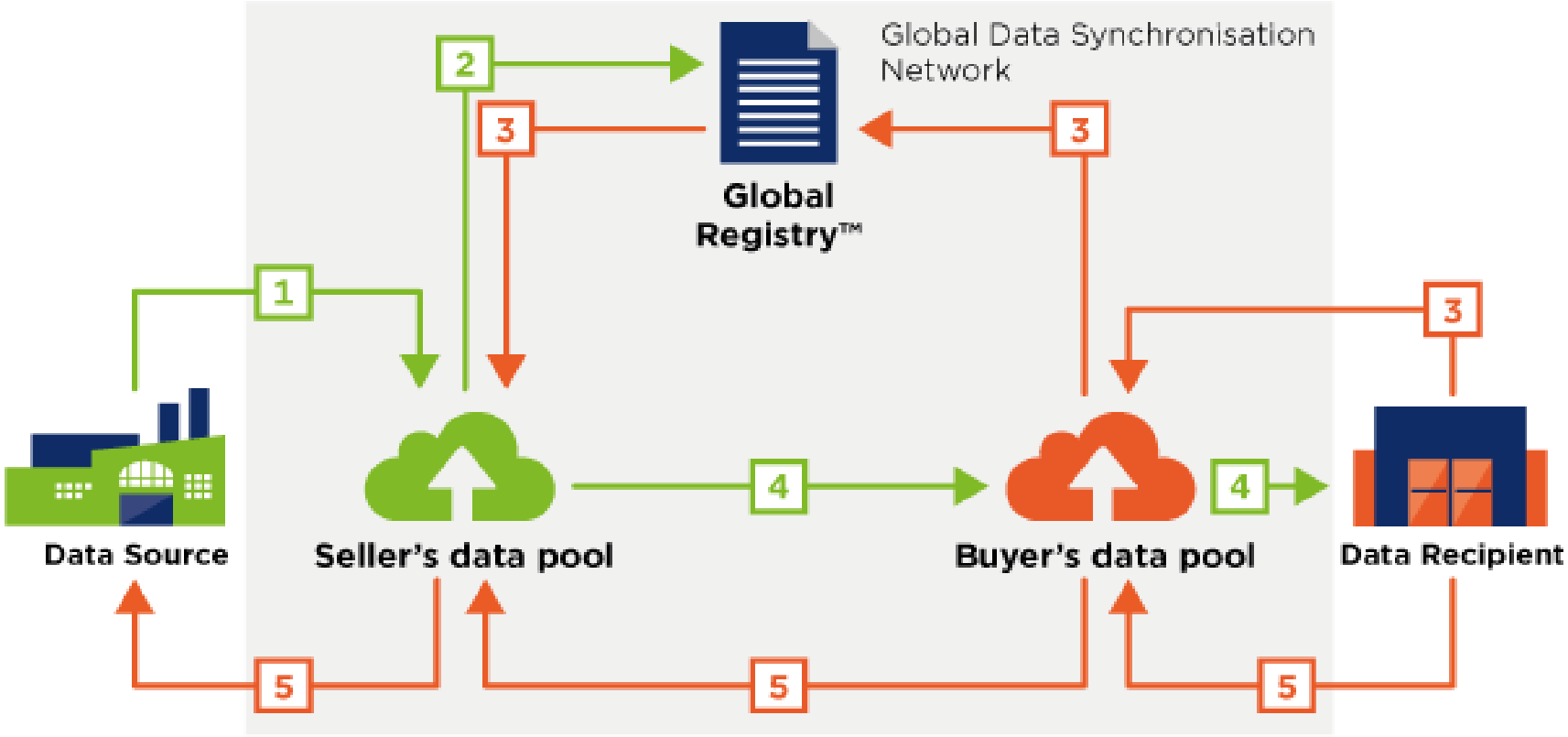
Healthcare Transformation Group

What is the GDSN?

- The GS1 Global Data Synchronization Network® (GDSN®) is a network of interoperable data pools enabling collaborating users to **securely synchronize master data** based on GS1 standards. GDSN supports **accurate, real-time data sharing** and trade item updates among subscribed trading partners.
- This means **organizations can have confidence** that when one of their suppliers or retailers updates their database, their own database is similarly updated as a result. Everyone has access to the same **continuously refreshed data**.

(Source: GS1)

How Does the GDSN Work?



1. Loading of company data
2. Registering of company data
3. Subscription to seller's data pool
4. Publishing of company data
5. Confirmation of receipt of company

(Source: GS1)

Why are IDNs and Federal Health Systems Participating?

What we are being told:

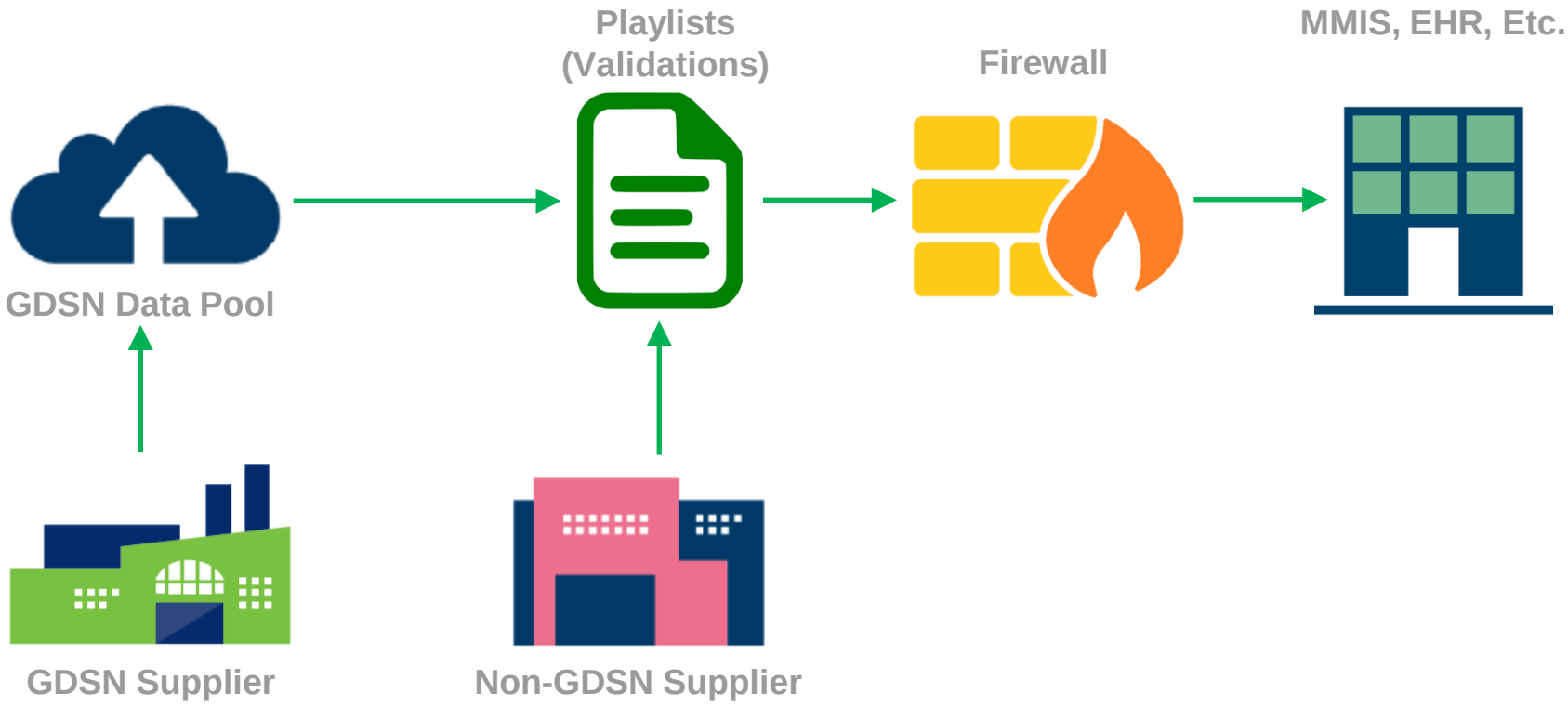
- Current processes are largely a combination of:
  - Manual form entry
  - Spreadsheet upload
- Most cases require incremental sourcing of product data:
  - Search the web
  - Call Suppliers
  - Requires constant data validation, scrubbing. etc.
- None of these are sustainable, repeatable processes
- None place responsibility for complete and accurate product data where they belong: the Manufacturer of the product.

Why are IDNs and Federal Health Systems Participating? continued

What We're Being Told:

- Complete and accurate records are needed for improved supply chain, operations, logistics, and value analysis
- The data IDNs need may not be exactly what regulators require
  - IDNs vary attribution of product data by product category and by IDN
- Complete and accurate data is needed to feed EHRs and meet federal requirements such as Meaningful Use…
- GDSN is Flexible
  - Growth from 151 to 3,000 attributes
  - Supports best practice
    - Built on GS1 Standards

Desired Aggregation and Delivery of Supplier Content



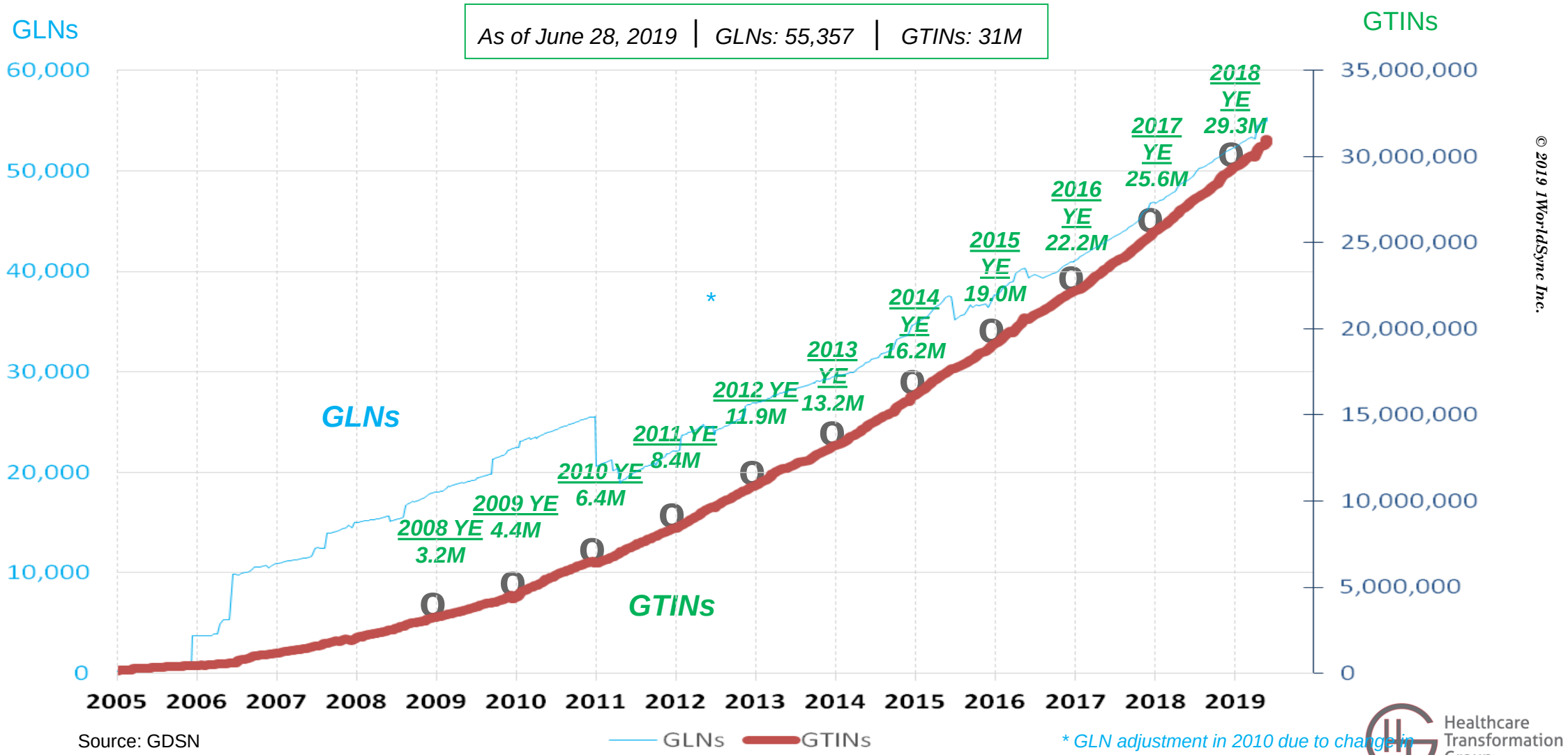
GDSN and Item Synchronization Update in Healthcare

GDSN Community Growth

WORLD SYNC

Healthcare Transformation Group

GDSN Community Growth: Steady GTIN and GLN Growth



Source: GDSN

* GLN adjustment in 2010 due to change in GDSN financial model

The Timing is Right

- Healthcare adoption is growing rapidly
  - Most major suppliers are onboard
    - Very few were onboard 5 years ago
- As of 30 Sep 2019: Source, GS1
  - 5,166 Healthcare GLN's in GDSN
  - 3,368,000 GTINs (Items)
    - 2,650,941 Medical Devices
    - 80,967 Pharma Items
    - 636,152 "Other" Items

The Timing is Right

With most Medical Device companies being global, major international activities are driving spectacular growth

- Regulatory Initiatives:
  - **United States, FDA UDI:** Med Device companies now have the data
  - **European Union, European Database on Medical Devices (EUDAMED):** 2.7 times the attributes required by the FDA (apx. 190 vs 70)
  - **United Kingdom, National Health Service (NHS):** Federal Hospitals
  - **Australia, National Product Catalogue (NPC):** Federal Hospitals

The Timing is Right

With most Medical Device companies being global, major international activities are driving spectacular growth (continued)

- GPO Activities:
  - **Belgium:** 4 University hospitals to pilot in 2019/20
  - **Switzerland:** Pilot with Bern Hospitals
  - **Denmark:** Starting GDSN Late 2019/2020
  - **Germany:** GPOs Prospitalia, P.E.G., Sana, AGKAMED & Clinic Partners
  - **France:** GPOs Resah and GAM
  - **Spain:** All federal hospitals in Catalonia and Navarra, and 4 more coming
  - **Netherlands:** Apx. 140 hospitals in test or production + 4 implant registries

The Timing is Right

With most Medical Device companies being global, major international activities are driving spectacular growth (continued)

- Coming MDRs
  - **China MDR**
  - **South Korea MDR**
  - **Saudi Arabia MDR**

GDSN and Rx PHARMA Source

GS1 US

The Global Language of Business

Healthcare Transformation Group

The Timing is Right:
GDSN Vital Attributes Workgroup – 2019

Problem Statement:

The Pharma industry must meet certain requirements for product serialization and traceability in 2019. In order to meet these requirements there is a need to share and maintain certain product details across supply chain trading partners. These pharma trading partners would like to answer the following:

The Timing is Right:
GDSN Vital Attributes Workgroup – 2019

How can Pharma Data Sources best use GDSN to interoperably share the necessary required attributes with Pharma Data Recipients to support EPCIS for compliance with DSCSA regulations? The scope is an initial population of data as well as a process for attribute change management.

Pilot Scope

- Manufacturers published Pharma product data via GDSN
- Validated attributes required for DSCSA and EPCIS
- Reconciliation of attribute values between Manufacturer submission and ABC consumption

Proof of Concept

- Focused on US traceability requirements
  - GDSN/EPCIS vital attributes identified in prior GS1 workgroup
- Pilot utilized agreed upon data set with Manufacturers
  - Small set of products in current portfolio
- Confirmed publisher and subscriber GLNs in scope
  - GLN subscription required to pass data between partners

Proof of Concept

- Case study performed in test environment
  - Recent copy of Production data
    - Provided accurate view of product master data

- Leveraged relationship between GDSN provider and ABC item setup partner

The Timing is Right

There is now data to send and a proven way to send/receive it

- The statement from medical device companies from 7-10 years ago at the start of the FDA UDI initiative, that they did not have detailed product data gathered, has materially diminished.
- Federal requirements have made medical device companies look at the gathering, maintenance and dissemination of product information in new and more comprehensive ways.
- **This is a major benefit for all IDNs**

Verathon	TRUE
Vyaire Medical, Inc.	TRUE
Welch Allyn Inc.	TRUE

Worldwide Innovations & Technologies, Inc.	TRUE
Wright Medical Technology	TRUE
Xodus Medical Inc.	TRUE
Zenoff Products	TRUE

Conclusions

- Complete and accurate product data is **CRITICAL** to supply chain and business operations of IDNs
- GDSN is a proven process for the synchronization of product data in a supply chain (55k companies, 32m products)
- GDSN provides a flexible model for adapting to industry and recipient specific needs (151 to 3000 attributes)
- While not a quick, easy, "silver bullet" solution, GDSN provides the best model for solving the problem at the source

Additional Resources

- Using GDSN in Healthcare Supply Chain
  - https://www.gs1us.org/gs1-us-library?Command=Core_Download&EntryId=919
- Business Process Map of GDSN Healthcare Attributes to Hospital Processes
  - http://www.ahrmm.org/advocacy/issues-topics/data-standards/files/business-process-map-gdsn-2012.pdf

Questions?

Appendix

- EHR: Electronic Health Record
- EUDAMED: European Database on Medical Devices
- GDSN: Global Data Synchronization Network
- GLN: Global Location Number
- GPO: Group Purchasing Organization
- GTIN: Global Trade Item Number
- IDN: Integrated Delivery Network
- MDR: Medical Device Regulation
- MMIS: Materials Management Information System
- UDI: Unique Device Identification

Collaboration Session

(Four Corner Drill – Phase 2)

Healthcare Transformation Group

Healthcare Transformation Group

Caring

Building UDI Into Longitudinal Data Project: BUILD Update / Final Report

HTG Summit 2019
October 24, 2019

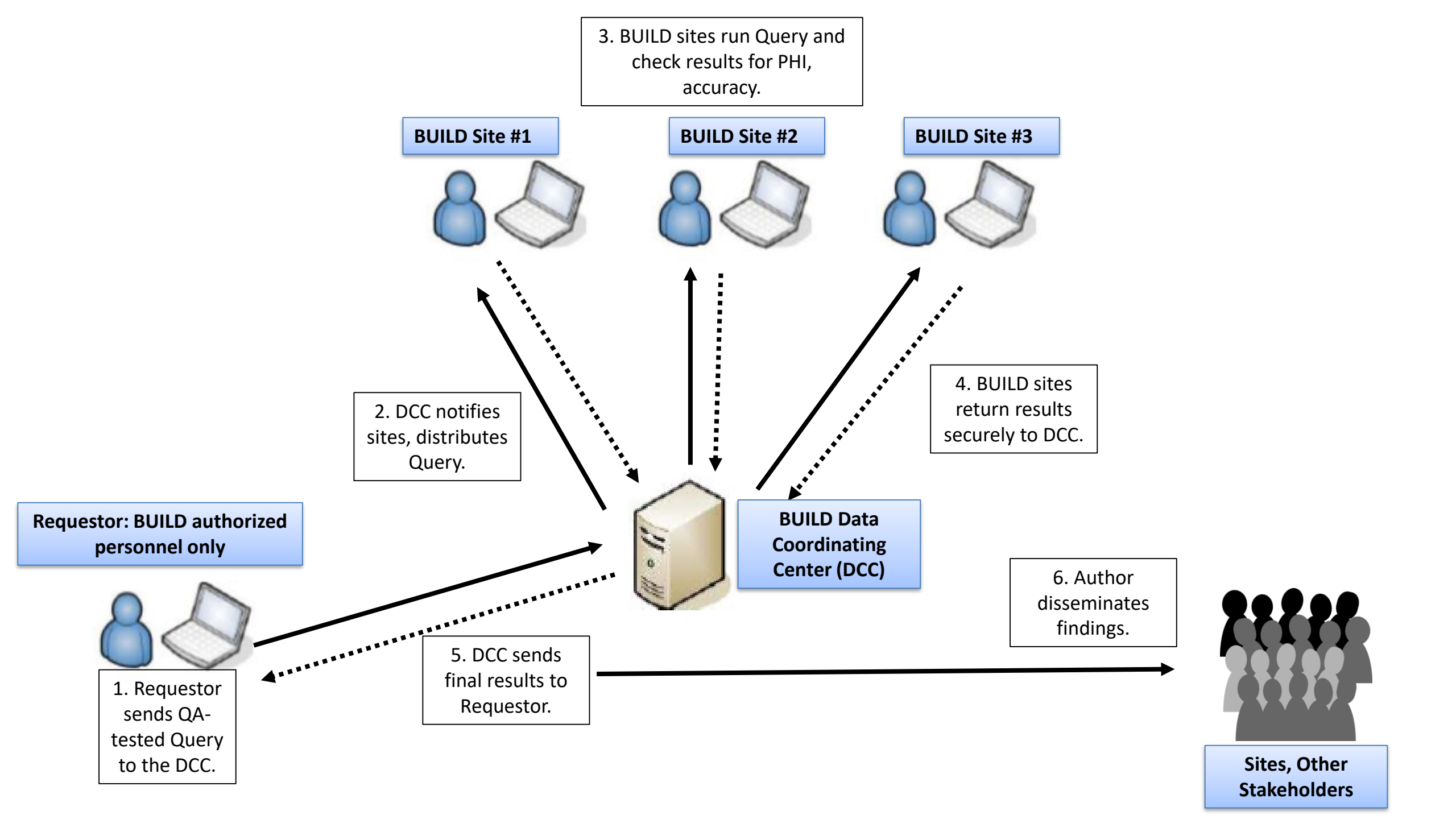
Jove Graham, PhD

Geisinger

BUILD Objectives

- Implement UDI into a UDI Research Database at multiple HTG health systems (Mercy, Geisinger, Intermountain)
- Establish a Distributed Data Network (DDN) of UDI-based device data among the HTG participants
- Execute test queries to demonstrate feasibility and usability of UDIRs and DDN for surveillance and research

- Phase I (2016-17), support from FDA
- Phase II (2017-18), support from Medtronic
- Phase III (2018-19), support from Johnson & Johnson


3. BUILD sites run Query and check results for PHI, accuracy.
BUILD Site #1
BUILD Site #2
BUILD Site #3
2. DCC notifies sites, distributes Query.
4. BUILD sites return results securely to DCC.
Requestor: BUILD authorized personnel only
BUILD Data Coordinating Center (DCC)
6. Author disseminates findings.
1. Requestor sends QA-tested Query to the DCC.
5. DCC sends final results to Requestor.
Sites, Other Stakeholders

UDIR Common Data Model

NDCR PCI Cath Registry
CORONARY_ANATOMY
CURRENT_COMMON
CURRENT_NON_STEMI
CURRENT_STEMI
DEMOGRAPHIC
DISCHARGE
EPISODE_OF_CARE
HISTORY_PAST
INHOSPITAL_EVENTS
PROC_CARDIAC_CATH

Sentinel CDM
CAUSE_OF_DEATH
DEATH
DEMOGRAPHIC
DEVICE
DIAGNOSIS
DISPENSING
ENCOUNTER
ENROLLMENT
INPATIENT_PHARMACY
INPATIENT_TRANSFUSION
LABORATORY_RESULT
PROCEDURE
VITAL_SIGNS

AUDI
ATTRIBUTES

GUDID
CONTACTS
DEVICE
DEVICESIZES
ENVIRONMENTAL
GMDNTERMS
IDENTIFIERS
PREMARKET
PRODUCTCODES
STERILIZATIONMETHOD

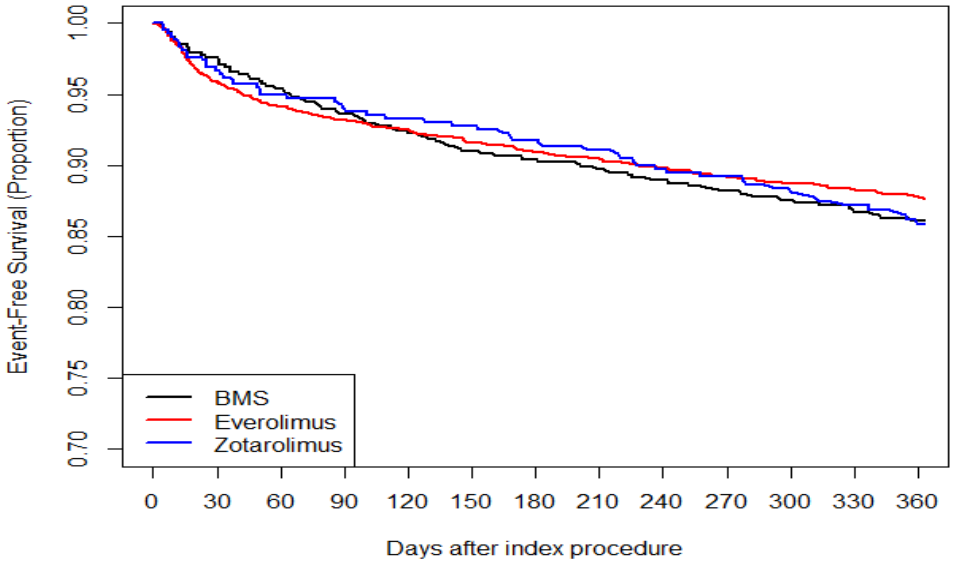
```
/**********  Extract data from UDIR ****************/
proc sql;
   create table meds_2017_males as
   select a.PATID
      , a.ndc
      , a.rxdate
      , a.rxsup
      , a.rxamt
   from UDIR.DISPENSING AS a
      inner join UDIR.DEMOGRAPHIC AS b
         on (a.PATID=b.PATID and b.SEX = "M")
   where a.rxdate between MDY(1,1,2017) and MDY(12,31,2017)
   order by a.MRN, a.rxdate, b.generic
   ;
quit;
```

Analysis – Feasibility Pilot

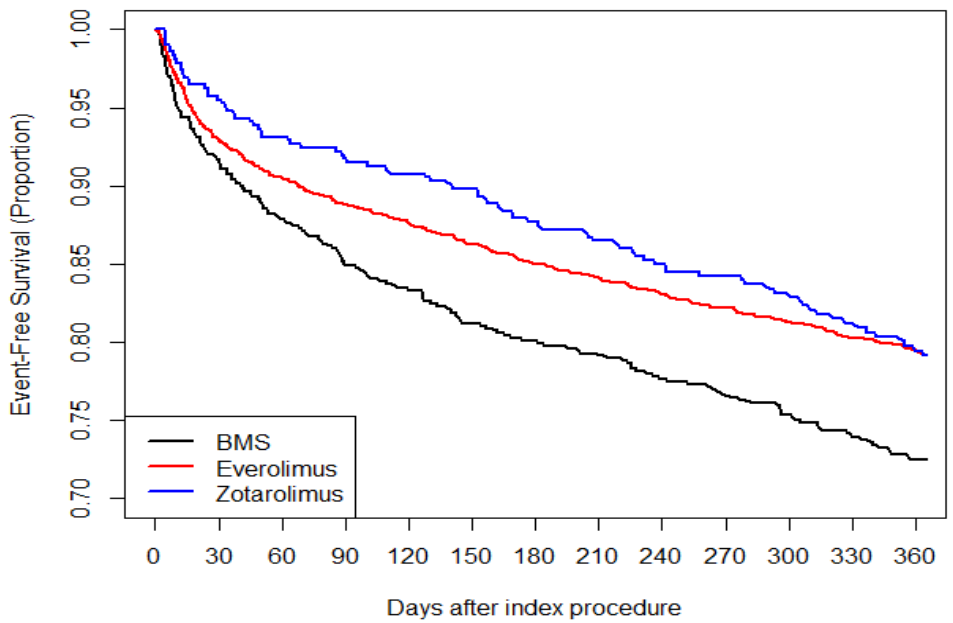
- Patients 18+ y.o., receiving either bare metal or drug (everolimus or zotarolimus) eluting stent 2012-18
- 32 baseline characteristics used to fit propensity score models at each site (probability of receiving stent A vs. B)
- Patients matched 1:1 on basis of score, sex, similar proc date
- Survival analysis (Cox) used to examine outcomes:
  - AMI, stroke, repeat PCI, CABG, all-cause mortality, composite

	Mercy		Geisinger		Intermountain	
	Patients	**Procedures**	**Patients**	**Procedures**	**Patients**	**Procedures**
Initial cohort with cath lab procedures	17,033	--	29,924	--	2,016	--
With coronary stent procedures	7,180	7,918	8,508	9,929	1,888	2,012
After joining AUDI attributes	7,180	7,917	8,308	9,674	1,887	2,010
After limiting to study time period, 2012-18	5,871	6,495	6,851	7,882	140	146
After removing those with mixed stents	5,712	6,303	6,568	7,476	130	134

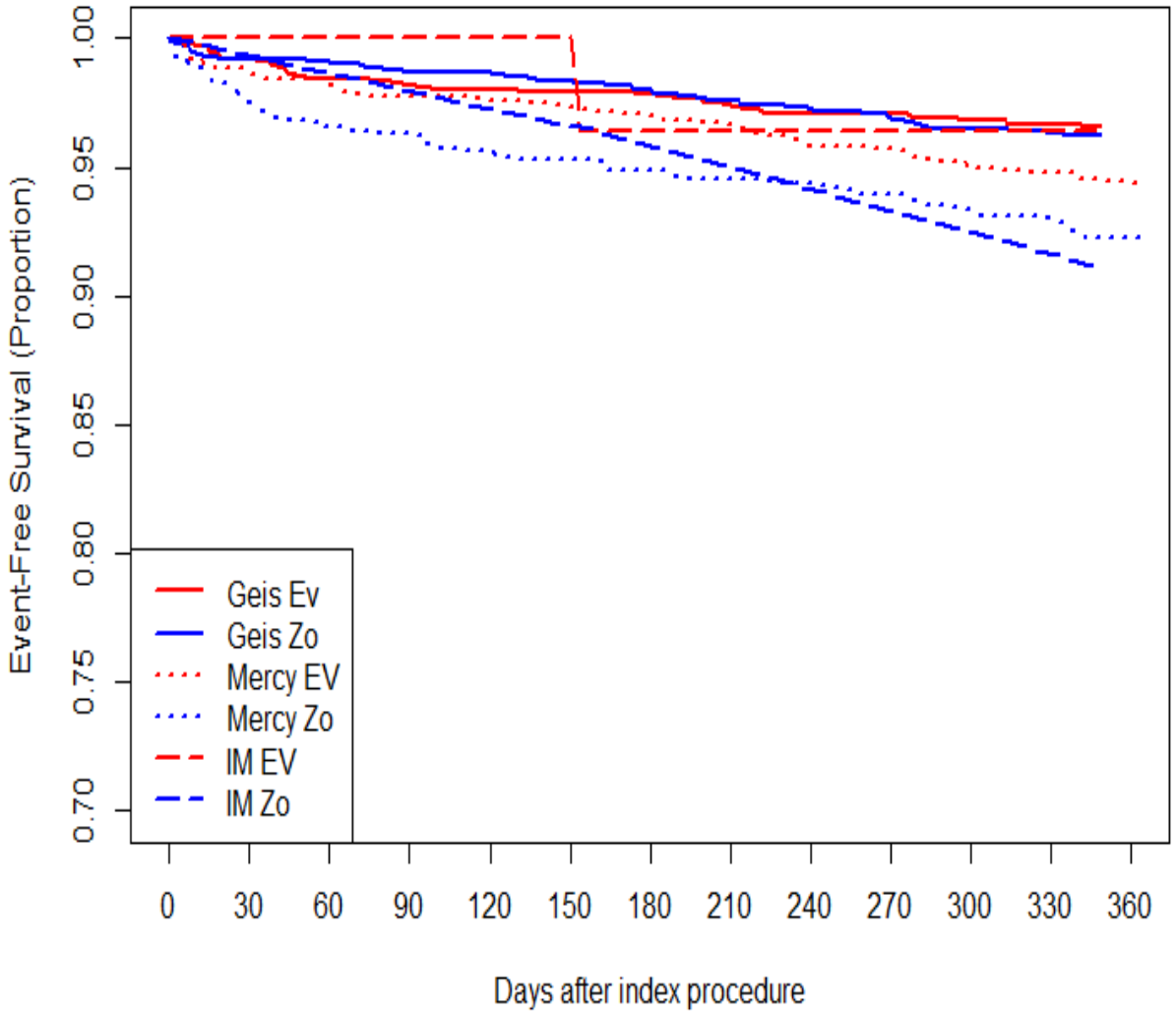
Revascularization (PCI) Procedures



Composite Outcome (AMI, Stroke, Procedure, Death)



All-Cause Mortality (matched cohorts at each site)



	Geisinger		Mercy		Intermountain	
	Hazard Ratio [95% CI]	p	Hazard Ratio [95% CI]	p	Hazard Ratio [95% CI]	p
Subsequent PCI	0.85 [0.69. 1.05]	0.14	1.18 [0.84, 1.66]	0.35	4.86 [0.76, 31.17]	0.10
CABG Procedure	1.31 [0.66, 2.61]	0.44	1.19 [0.53, 2.67]	0.67	*	*
All-Cause Mortality	1.06 [0.68, 1.66]	0.78	1.41 [0.87, 2.29]	0.16	2.12 [0.18, 24.42]	0.55
Composite Endpoint	0.94 [0.78, 1.13]	0.53	1.12 [0.88, 1.44]	0.37	3.02 [0.66, 13.89]	0.16

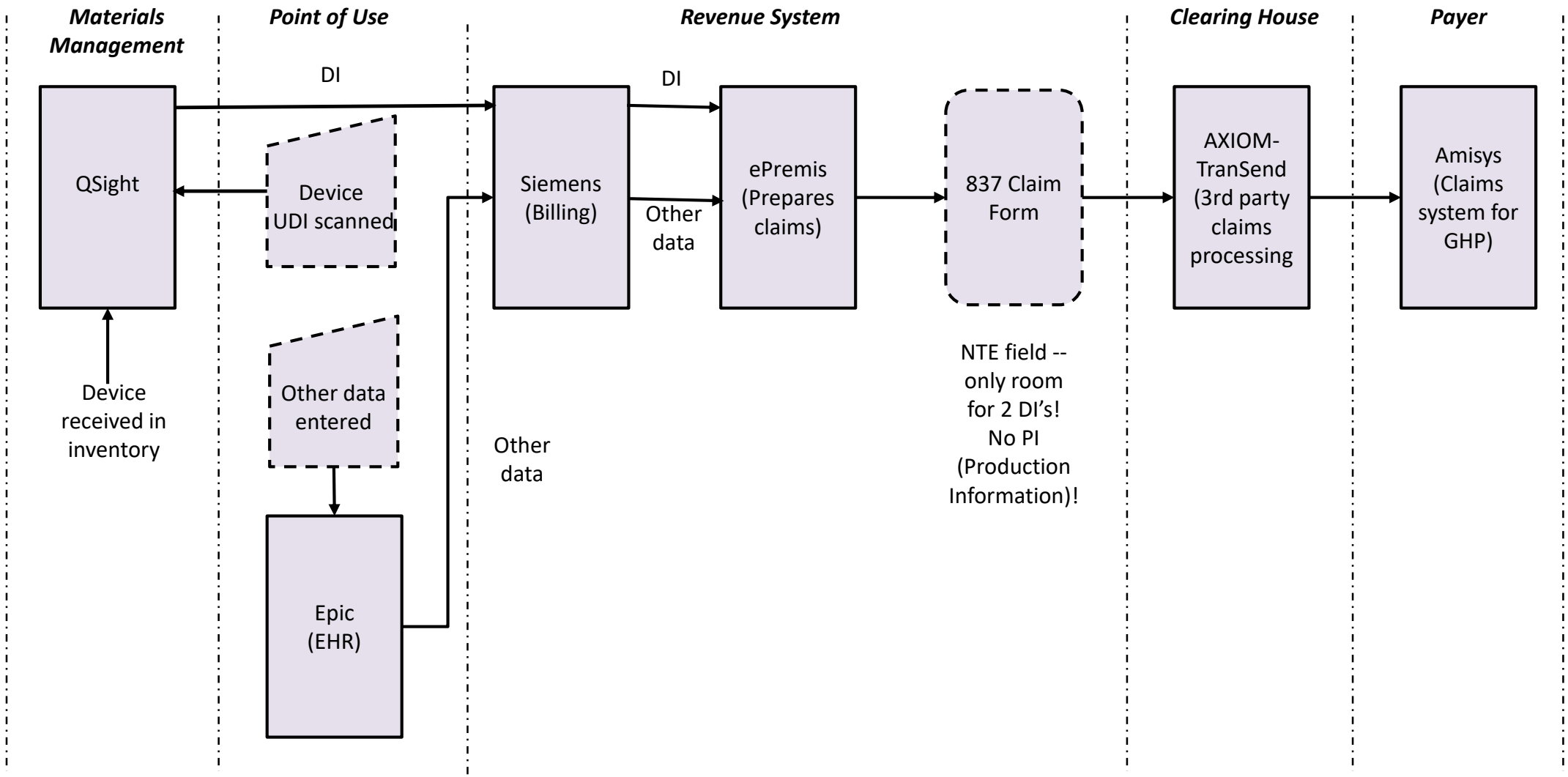
Takeaways / Next Steps

- Addition of UDI (+link to GUDID, AUDI) allow large-population comparisons of stent types that were not previously possible with just EHR and procedure codes
- Real-world evidence from 3 large HTG systems generally agree with randomized trial results
- Bare-metal stents being replaced, over time, with modern drug-eluting stents which appear to have better mortality, composite results

- Final BUILD report delivered 6/30/19
- ACC abstract, journal manuscript(s) in progress

- Future ideas: Other devices (Cardiology, Orthopedics); Linking to a PCORNet patient-powered network; Use of DELTA for prospective surveillance

UDI to Claims



MEDTECHDIVE Deep Dive Library Events Jobs Topics

BRIEF

Key committee pitches adding UDIs to payer claim forms, called 'huge step'

THE PEW CHARITABLE TRUSTS SEARCH MENU

The Pew Charitable Trusts / Research & Analysis / Researchers Design System for Adding Device IDs to Health Insurance Claims

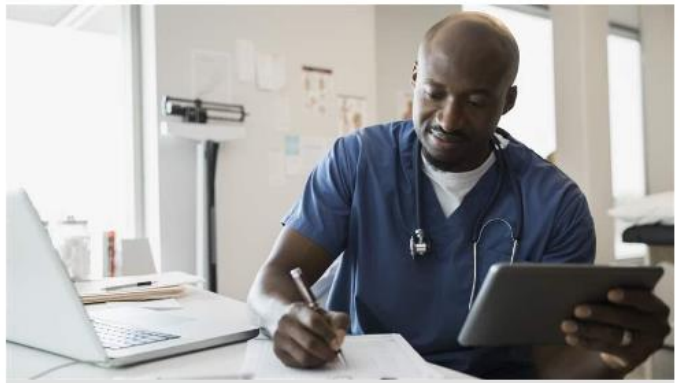
ANALYSIS

Researchers Design System for Adding Device IDs to Health Insurance Claims

Including device data on claim forms would improve patient safety and device quality

May 17, 2017 | Medical Device Initiative | By Josh Rising

SHARE



© Getty Images

Researchers at Brigham and Women's Hospital in Boston who are studying ways to improve the safety of cardiac stents and artificial joints have designed a system to track medical devices on insurance claim forms and detect problems with these products more quickly. The system documents in claims forms medical device identifiers, which indicate the manufacturer and model of a device used. Insurance claims are often used by researchers to study health outcomes, but they currently lack information on which devices are being implanted. Including device identifiers in claims would make it easier to quickly identify problems with medical implants.

The researchers, who described their process in a white paper funded by The Pew Charitable Trusts, found that documenting device identifiers in claims is "straightforward." This can be done, they said, without incorporating this

About the Author

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Director
Health Care Programs
The Pew Charitable Trusts
@joshrising

Analysis

Medical Device Identifiers Can Help Medicare Improve Patient Safety, Health Care

But claims forms must be changed to capture important data

Our Team

Mercy
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- Jim Roach
- Andrew McKinnon
- Angelique Zeringue
- Kerry Bommarito
- Benjamin Dummitt

Geisinger
- **Jove Graham**
- Kevin Capatch

Intermountain
- **Dr. Brent Muhlestein**
- Stacey Knight
- Heidi May
- Jon-David Ethington

Medtronic
- Bart Phillips
- Kara Southall
- Edgar Simard
- Joao Monteiro

Johnson & Johnson
- Jesse Berlin
- Iftekhar Kalsekar
- Paul Coplan

FDA
- Terrie Reed
- Behnaz Menai
- Greg Pappas
- Alex Hu
- Erika Tang

Duke
- **Dr. James Tcheng**

Arizona State University
- **Dr. Natalia Wilson**

BUILD: Leading Practices

Point of Care Capture of UDI for Implantable Devices

Natalia Wilson, MD MPH

BUILD Co-Investigator

Site Lead for BUILD: Leading Practices

Broad Problem

Gaps in development of a comprehensive UDI system in US health care

Study Focus

Knowledge gap in hospital systems for UDI implementation at the POC for implantable devices

Study Goals

Document leading practices for UDI implementation, strategies to address gaps, & needed next steps

BUILD: Leading Practices Tasks

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Arizona State University

1. Establishment of a multi-stakeholder consortium of UDI leaders (BUILD Consortium)
2. Creation of BUILD webpages (http://mdepinet.org/build/)
3. Performance of interviews of UDI leaders in hospital systems that had implemented UDI at the POC for implantable devices
4. Creation of a Point of Care Capture of UDI for Implantable Devices document with Roadmap, Gaps/Challenges & Needed Next Steps

Methodology

1. 10 leading hospital systems included
2. 24 semi-structured interviews conducted
3. Survey on hospital demographics obtained
4. ASU IRB oversight
5. Qualitative data
    - Thematic analysis
    - IRR established
6. Quantitative data
    - Aggregated in Microsoft Excel
    - Descriptive statistics

Methodology (cont.)

7. BUILD Consortium
    - Expert panel, April 3, 2019 meeting
8. Point of Care Capture of UDI for Implantable Devices document informed by interview data, survey data, April 3, 2019 outcomes, & post-meeting reviews

What's in the Roadmap Document?

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Arizona State University

- Project History
- Methodology & Analysis
- Extensive Data
- Implementation Roadmap
- Gaps & Challenges
- Needed Next Steps

Plan: Dissemination - posting on FDA website; share with the UDI community, academic publications, presentations

Data on Represented Hospital Systems (n=10)

- Majority
  - UDI implementation system level initiative
  - Non-governmental, NFP
  - Contained AMC & health care plan
- Range of US location, size & revenue
- 80% using barcode scanning
- All capturing in electronic systems at POC
- Most using Epic as EHR & Infor/Lawson or Peoplesoft as ERP

Data on Interviewees (n=24)

- Focus areas: clinical, supply chain, IT, operational
  - Majority had 2-3 focus areas
- Positions: executives, directors, managers, clinicians
- 25 % with direct clinical background

Implementation Roadmap

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Arizona State University

KEY COMPONENTS & STEPS

FOUNDATIONAL THEMES

Holistic Vision
Interprofessionalism
Collaboration
Communication
Integrity
Innovation
Resilience
Sustainability

UDI USE

Clinical
Population Health
Operational
Safety Surveillance
Research
Device Evaluation

OUTCOMES

Improved Patient Care

Improved Population Health

Lower Costs

Gaps & Challenges

Identified Areas

1. Clinical
    - Resistance, confusion, frustration
    - Limited education on value & use
2. Information Technology
    - Interoperability, resistance, lack of ownership
    - IT system variability between different hospital systems
3. GUDID
    - Limitations

Gaps & Challenges

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Arizona State University

Identified Areas

4. Manufacturers
   - Lack of consistency, collaboration, ownership
5. Support for UDI Implementation
   - Needed time, HR, prioritization
6. Overall UDI System
   - Policy drivers, Innovation, Hospital system implementation, Supporting structure

Needed Next Steps

CHALLENGE AREA	PILOT PROJECTS	OTHER
Clinical	• Creation of durable, publicly accessible education materials/content for clinicians, including education modules and case studies for continuing education (CME, CEU) • An interdisciplinary project involving clinical end-users and manufacturers to inform medical device labelling based on experience at the POC • Documentation and mapping of best practices for integrating UDI capture into clinical workflows.	• Engagement of marketing expert(s) to assess best dissemination methods • Use of social media • Work towards a manufacturer requirement for “UDI” to be placed on the device label next to what needs to be scanned • Barcode training as a requirement for new staff on-boarding
IT	• Study and mapping of an optimal hospital system IT architecture for UDI implementation for implantable devices at the POC • Study of hospital system-IT vendor relationships and strategies to address challenges	• Creation of a catalog on IT vendors and systems indicating functionality for a UDI system; gaps; and ability to compensate for common gaps • Creation of a UDI-focused IT vendor group
GUDID	• Survey of hospital systems’ use of AccessGUDID data, barriers faced, and perceived limitations	• Direct work with manufacturers
Manufacturers	• Assessment of hospital system use of a national scorecard or standard questions on manufacturer UDI compliance and functionality	• Standard inclusion of UDI-focused requirements in contracting • Direct work with manufacturers including towards a manufacturer requirement for “UDI” to be placed on the device label next to what needs to be scanned
Support	• Comprehensive workflow analysis of UDI implementation • Creation of durable, publicly accessible education materials/content for clinicians, those in leadership, financial and other operational roles, including education modules and case studies for continuing education (CME, CEU)	• Job description for the UDI Initiative Leader • Barcode training as a requirement for new staff on-boarding • Organizational policy change and guidelines
Overall UDI System	• Assess best methods for education & marketing • Creation of durable, publicly accessible education materials/content for broad stakeholders inclusive of generalizable slide decks, short videos, TED talks, gamification • Studies linking UDI use to outcomes • Assessment/creation of metrics	• Focus on policy drivers including Joint Commission mandated nursing documentation; inclusion of UDI in required quality metrics • Comprehensive delineation of funding opportunities/resources • Collaboration of UDI-focused researchers for further research and funding • Expansion of involved disciplines in research, e.g. health economists • Development of a sustainability plan

Thank you

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DSCSA Blockchain Update

Bob Celeste

Center for Supply Chain Studies

The Tools & Framework we will Discuss Are applicable to:

DSCSA

Recall

Clinical Trials

Research Access

Medical Device Identification & Access

Government Licensing
(FDA, DEA, State BoP, etc.)

Patient Identification

Prescriptions

Caregiver Authentication

Patient Health Record Access

Vendor Credentialing

Medical Provider Credentialing

Employee Access Management

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Neutral, Non-Profit, 501(c)(6)
Exploration and Education
ReferenceModel based Studies

VirtualPilot™, and ReferenceModel™ Library

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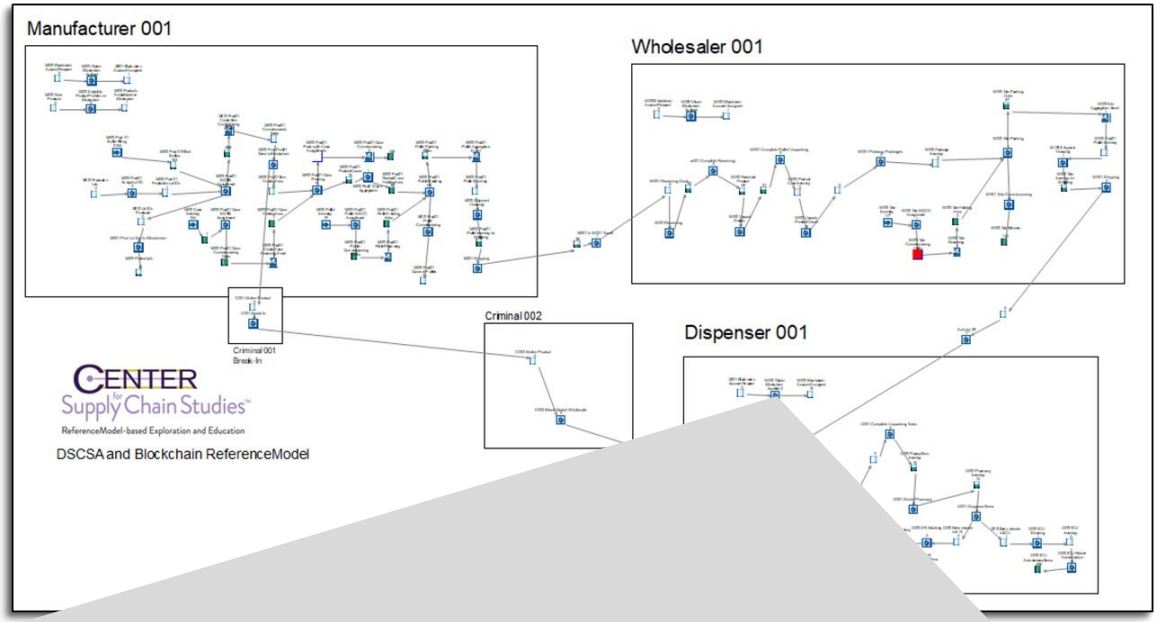
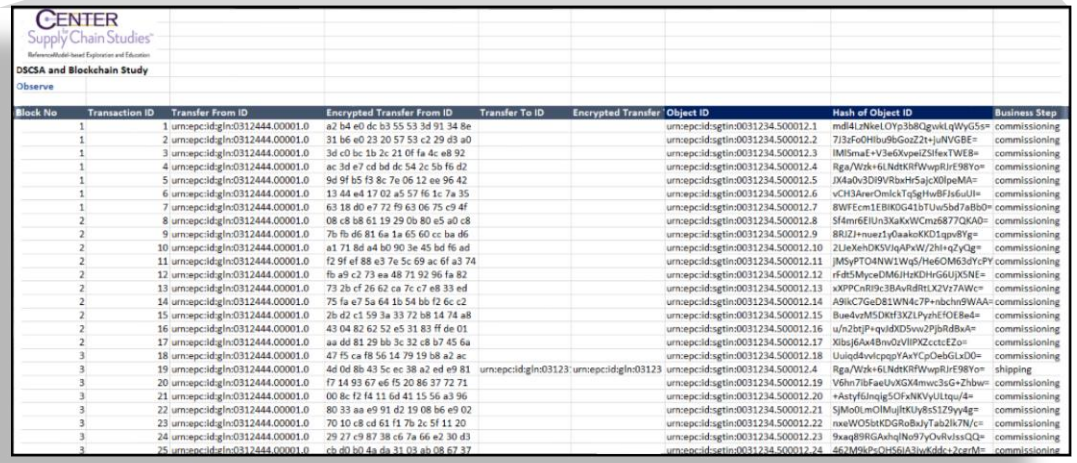
ReferenceModel based Studies

Virtual Pilots: Manage complexity and keep discussions in context




CENTER
Supply Chain Studies
ReferenceModel-based Exploration and Education

DSCSA and Blockchain Study

Observe

Block No	Transaction ID	Transfer From ID	Encrypted Transfer From ID	Transfer To ID	Encrypted Transfer	Object ID	Hash of Object ID	Business Step
	1	1 urn:epc:id:sgln:0312444.00001.0	a2 b4 e0 dc b3 55 53 3d 91 34 8e			urn:epc:id:sgtin:0031234.500012.1	mdl4LzNkeLOYp3b8QgwkLqWyG5s=	commissioning
	1	2 urn:epc:id:sgln:0312444.00001.0	31 b6 e0 23 20 57 53 c2 29 d3 a0			urn:epc:id:sgtin:0031234.500012.2	7J3zFo0HIbu9bGozZ2t+juNVGBE=	commissioning
	1	3 urn:epc:id:sgln:0312444.00001.0	3d c0 bc 1b 2c 21 0f fa 4c e8 92			urn:epc:id:sgtin:0031234.500012.3	IMlSmaE+V3e6XvpeiZSIfexTWE8=	commissioning
	1	4 urn:epc:id:sgln:0312444.00001.0	ac 3d e7 cd bd dc 54 2c 5b f6 d2			urn:epc:id:sgtin:0031234.500012.4	Rga/Wzk+6LNdtKRfWwpRJrE98Yo=	commissioning
	1	5 urn:epc:id:sgln:0312444.00001.0	9d 9f b5 f3 8c 7e 06 12 ee 96 42			urn:epc:id:sgtin:0031234.500012.5	JX4a0v3Di9VRbxHr5ajcX0lpeMA=	commissioning
	1	6 urn:epc:id:sgln:0312444.00001.0	13 44 e4 17 02 a5 57 f6 1c 7a 35			urn:epc:id:sgtin:0031234.500012.6	vCH3ArerOmlckTq5gHwBFJs6uUI=	commissioning
	1	7 urn:epc:id:sgln:0312444.00001.0	63 18 d0 e7 72 f9 63 06 75 c9 4f			urn:epc:id:sgtin:0031234.500012.7	8WFEcm1EBIK0G41bTUw5bd7aBb0=	commissioning
	2	8 urn:epc:id:sgln:0312444.00001.0	08 c8 b8 61 19 29 0b 80 e5 a0 c8			urn:epc:id:sgtin:0031234.500012.8	Sf4mr6EIUn3XaKxWCmz6877QKA0=	commissioning
	2	9 urn:epc:id:sgln:0312444.00001.0	7b fb d6 81 6a 1a 65 60 cc ba d6			urn:epc:id:sgtin:0031234.500012.9	8RJZI+nuez1y0aakoKKD1qpv8Yg=	commissioning
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	2	11 urn:epc:id:sgln:0312444.00001.0	f2 9f ef 88 e3 7e 5c 69 ac 6f a3 74			urn:epc:id:sgtin:0031234.500012.11	JMSyPTO4NW1Wq5/He6OM63dYcPY	commissioning
	2	12 urn:epc:id:sgln:0312444.00001.0	fb a9 c2 73 ea 48 71 92 96 fa 82			urn:epc:id:sgtin:0031234.500012.12	rFdt5MyceDM6JHzKDHrG6UjX5NE=	commissioning
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	2	18 urn:epc:id:sgln:0312444.00001.0	47 f5 ca f8 56 14 79 19 b8 a2 ac			urn:epc:id:sgtin:0031234.500012.18	Uuiqd4vvlcpqpYAxYCpOebGLxDO=	commissioning
	3	19 urn:epc:id:sgln:0312444.00001.0	4d 0d 8b 43 5c ec 38 a2 ed e9 81	urn:epc:id:sgln:03123	urn:epc:id:sgln:03123	urn:epc:id:sgtin:0031234.500012.4	Rga/Wzk+6LNdtKRfWwpRJrE98Yo=	shipping
	3	20 urn:epc:id:sgln:0312444.00001.0	f7 14 93 67 e6 f5 20 86 37 72 71			urn:epc:id:sgtin:0031234.500012.19	V6hn7IbFaeUvXGX4mwc3sG+Zhbw=	commissioning
	3	21 urn:epc:id:sgln:0312444.00001.0	00 8c f2 f4 11 6d 41 15 56 a3 96			urn:epc:id:sgtin:0031234.500012.20	+AstyfiJlnqJg5OFxNKVyULtqu/4=	commissioning
	3	22 urn:epc:id:sgln:0312444.00001.0	80 33 aa e9 91 d2 19 08 b6 e9 02			urn:epc:id:sgtin:0031234.500012.21	SjMo0LmOIMujltKUy8s5lZ9yy4g=	commissioning
	3	23 urn:epc:id:sgln:0312444.00001.0	70 10 c8 cd 61 f1 7b 2c 5f 11 20			urn:epc:id:sgtin:0031234.500012.22	nxeWO5btKDGRoBxJyTab2Ik7N/c=	commissioning
	3	24 urn:epc:id:sgln:0312444.00001.0	29 27 c9 87 38 c6 7a 66 e2 30 d3			urn:epc:id:sgtin:0031234.500012.23	9xaq89RGAxhqlNo97yOvRvJssQQ=	commissioning
	3	25 urn:epc:id:sgln:0312444.00001.0	cb d0 b0 4a da 31 03 ab 08 67 37			urn:epc:id:sgtin:0031234.500012.24	462M9kPsQH56lA3lwKddc+2cerM=	commissioning

Explore

Behavior, Process, Information, Financials

Adapt

Market, Regulatory, Technology

Prepare

Disasters, Human Errors, Criminal Activity

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STUDIES

STUDY: DSCSA & MDM

VirtualPilot was completed in the summer of 2017. The Study Team's White Paper, ***"Demonstrating how Master Data Management can be used in support of DSCSA Requirements,"*** *is available now.*

STUDY: Blockchain for Cold Chain

Study will incorporate the ability to capture temperature, light and vibration data from the Internet of Things (IoT), and provide data collection solutions for verifying real-time status of supply chain items.

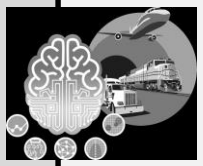
STUDY: DSCSA & Blockchain

Team is examining the use of blockchain technology as a possible way to address some of the unresolved DSCSA data security issues facing the U.S. pharma industry.

STUDY: Brand Protection & Supply Chain Security

STUDY: DSCSA & Blockchain 2

Phase 2 will apply the scenarios, processes and information flows identified in *DSCSA & Blockchain: Phase 1.*



Study: Identity and Supply Chain

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Agenda

DSCSA & Blockchain

The real challenges

Addressing the challenges

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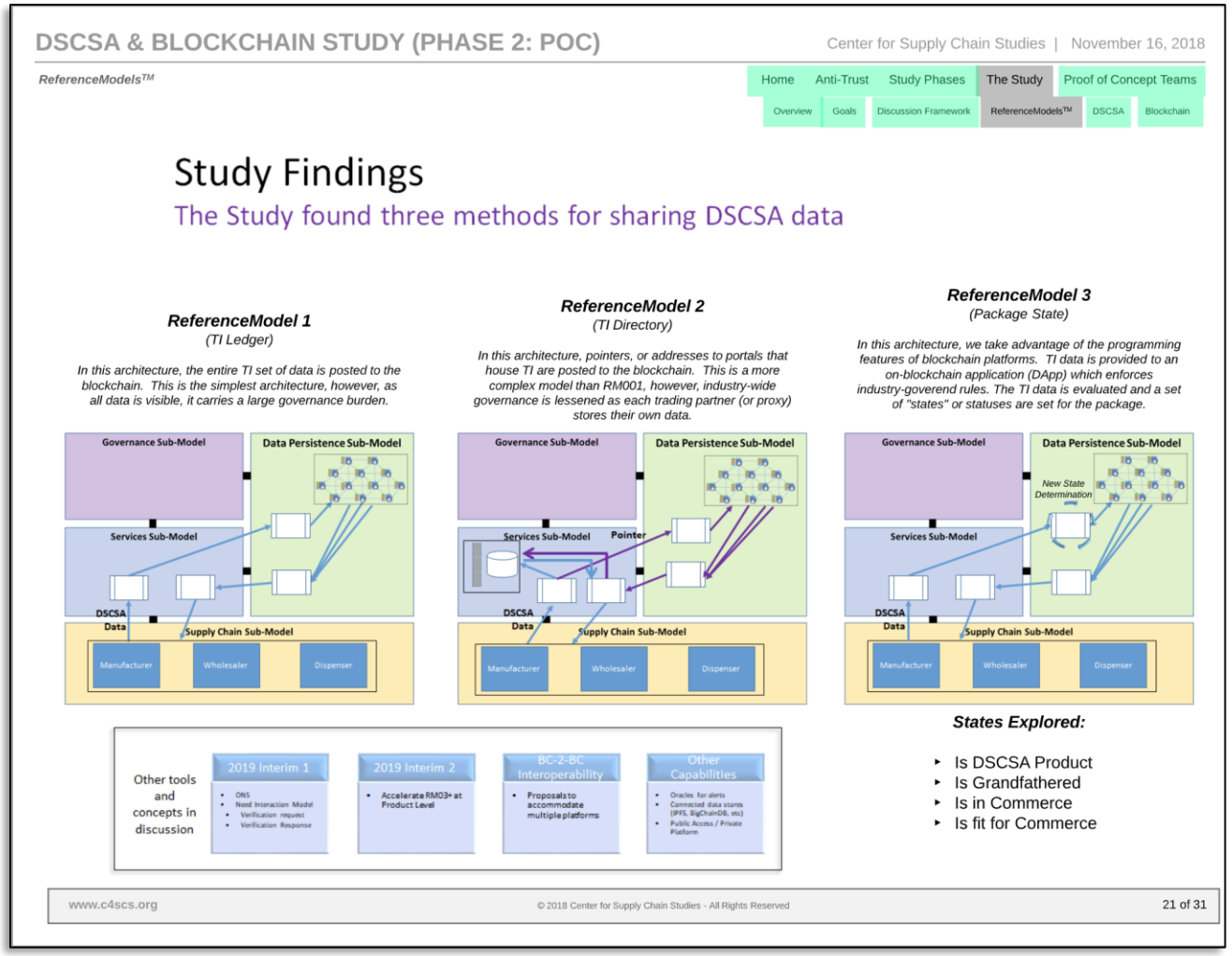
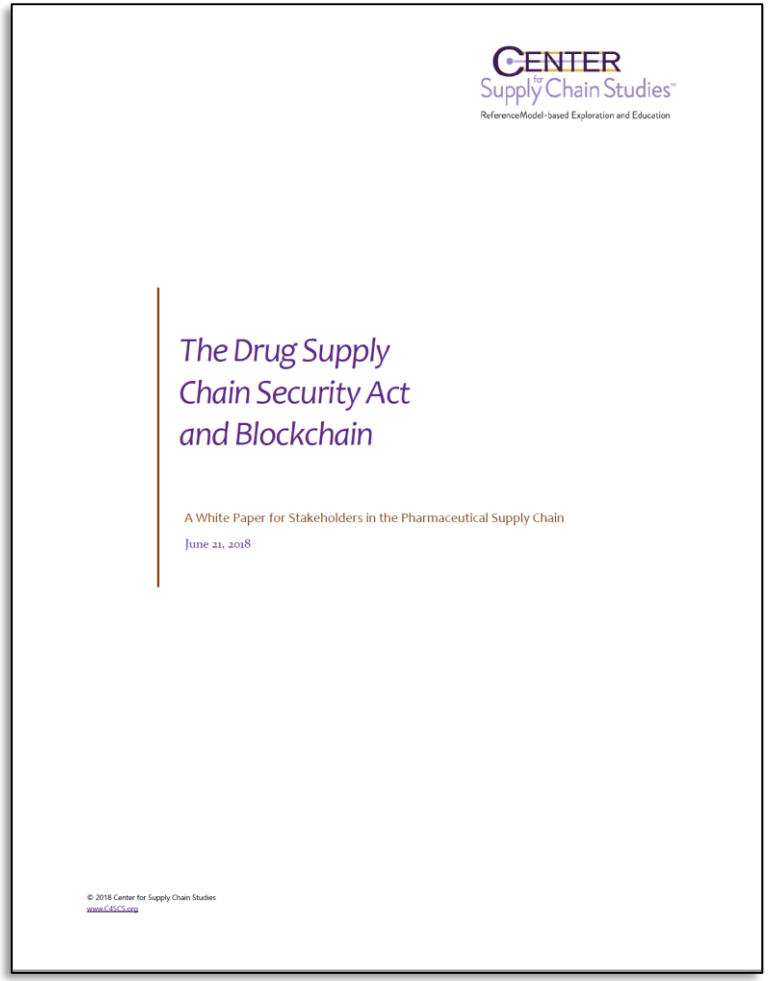
2017-2018: DSCSA & Blockchain





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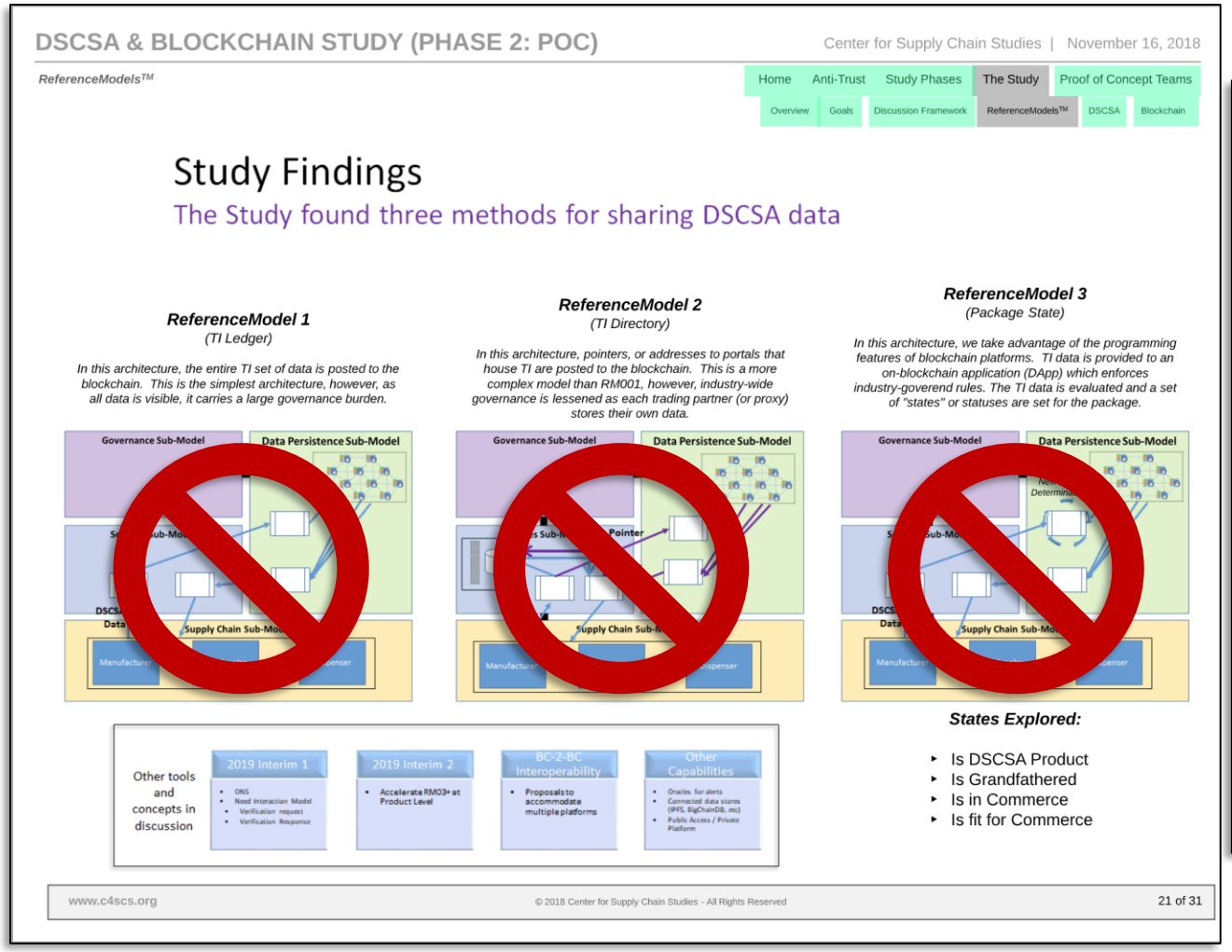
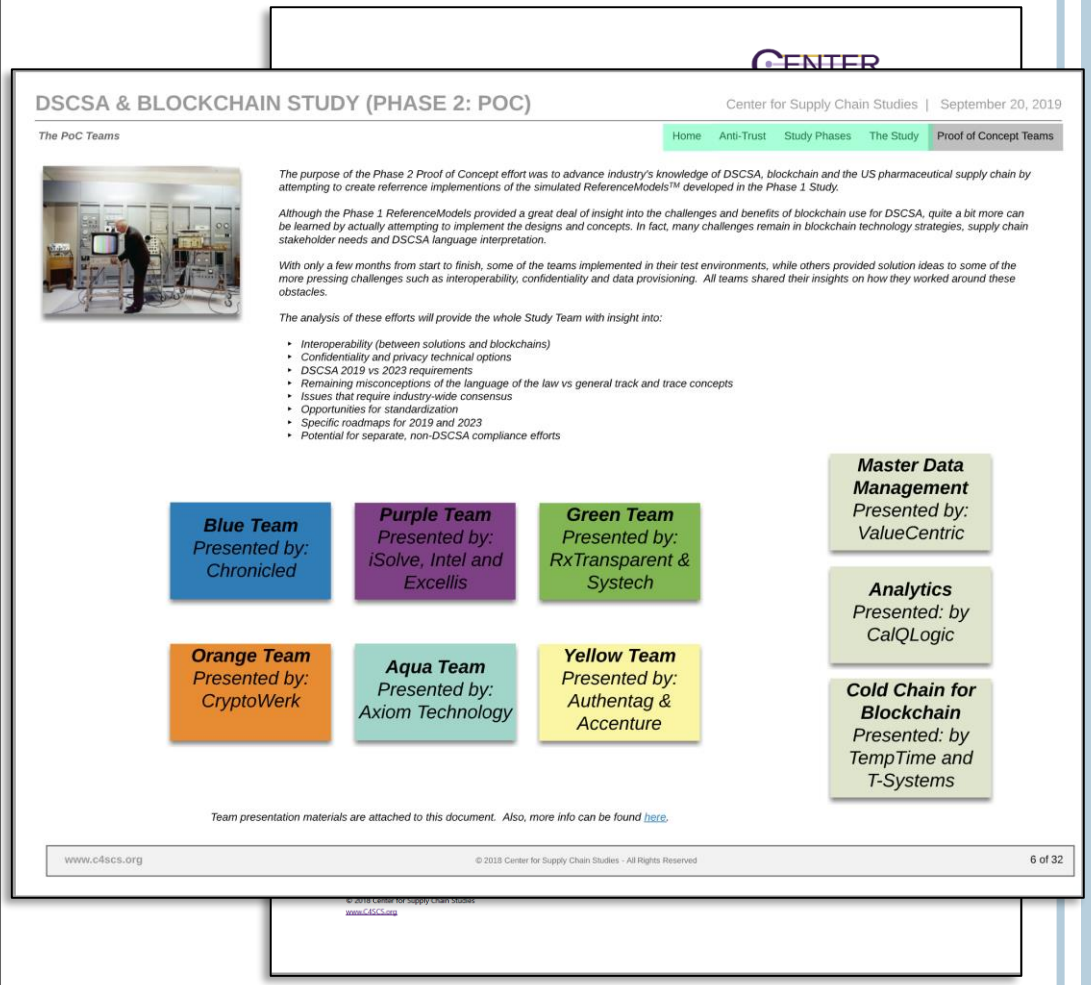
2018-2019: DSCSA & Blockchain 2





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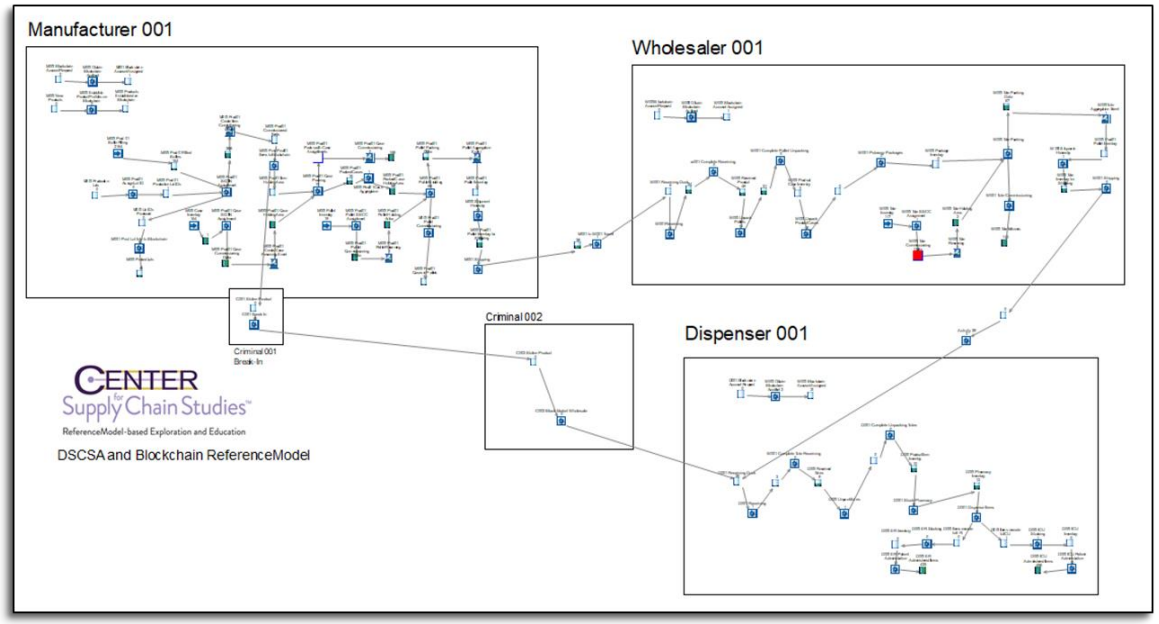

Back to the Drawing Board

DSCSA

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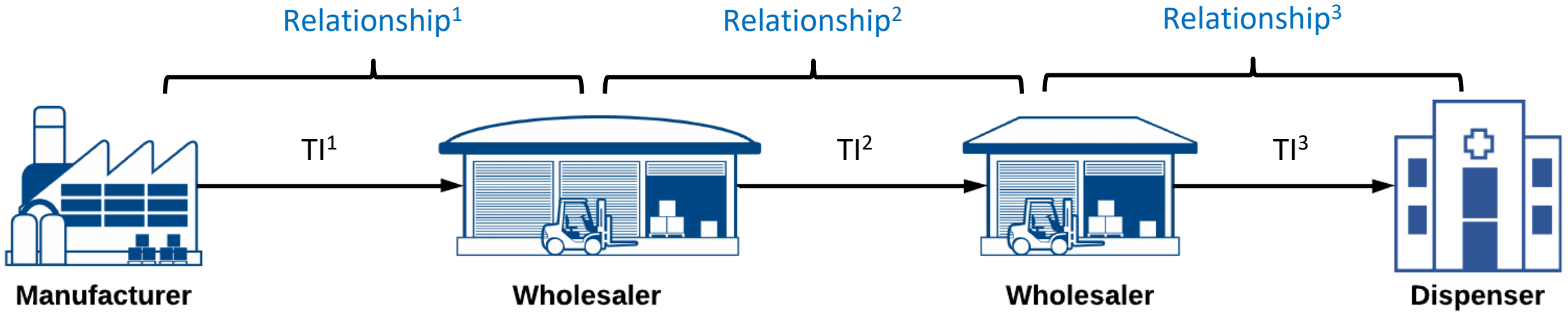
Existing Relationships

are required to share Transaction Information



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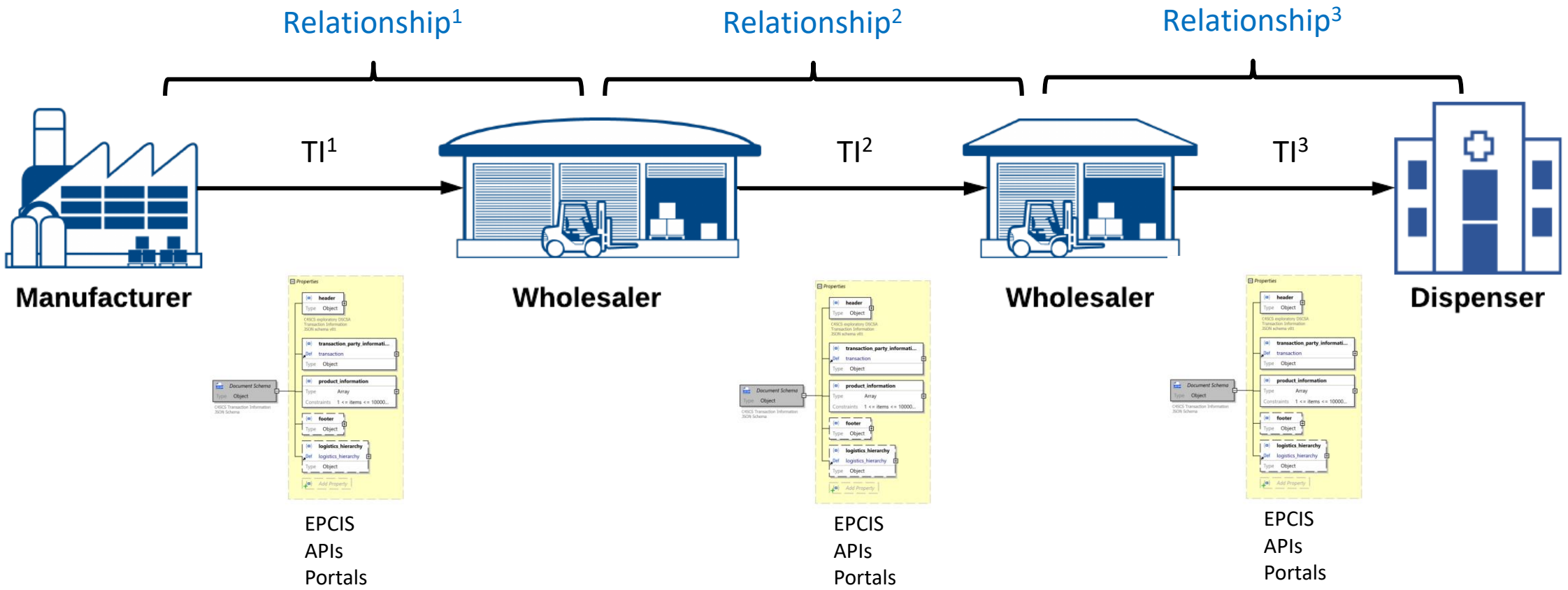
Existing Relationships

Can make use of current tools



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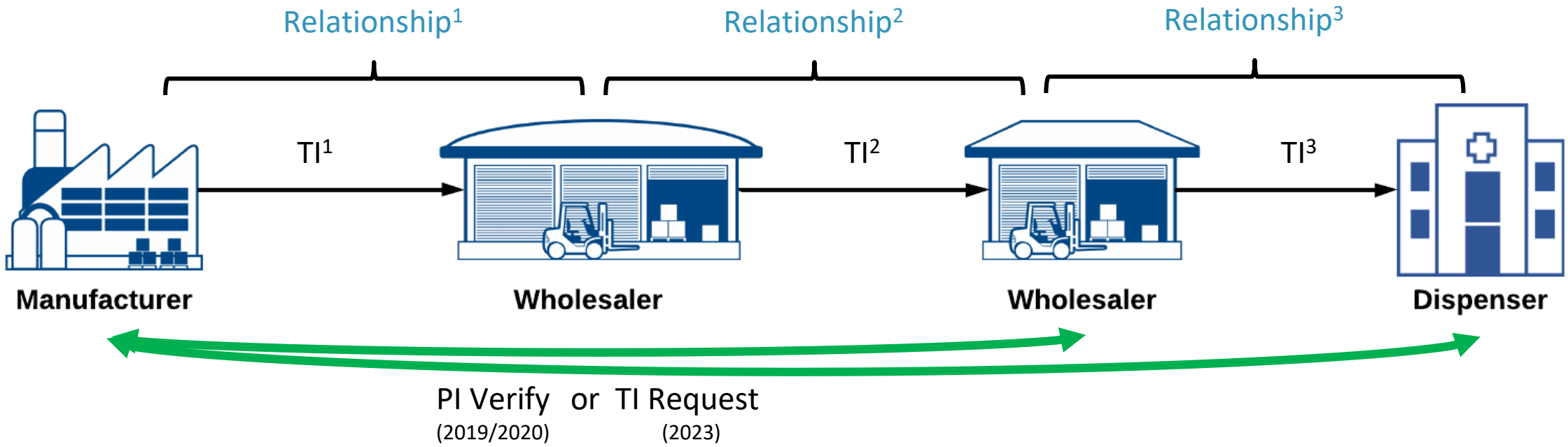
The real challenge

verifying Product Information and retrieving previous transaction information



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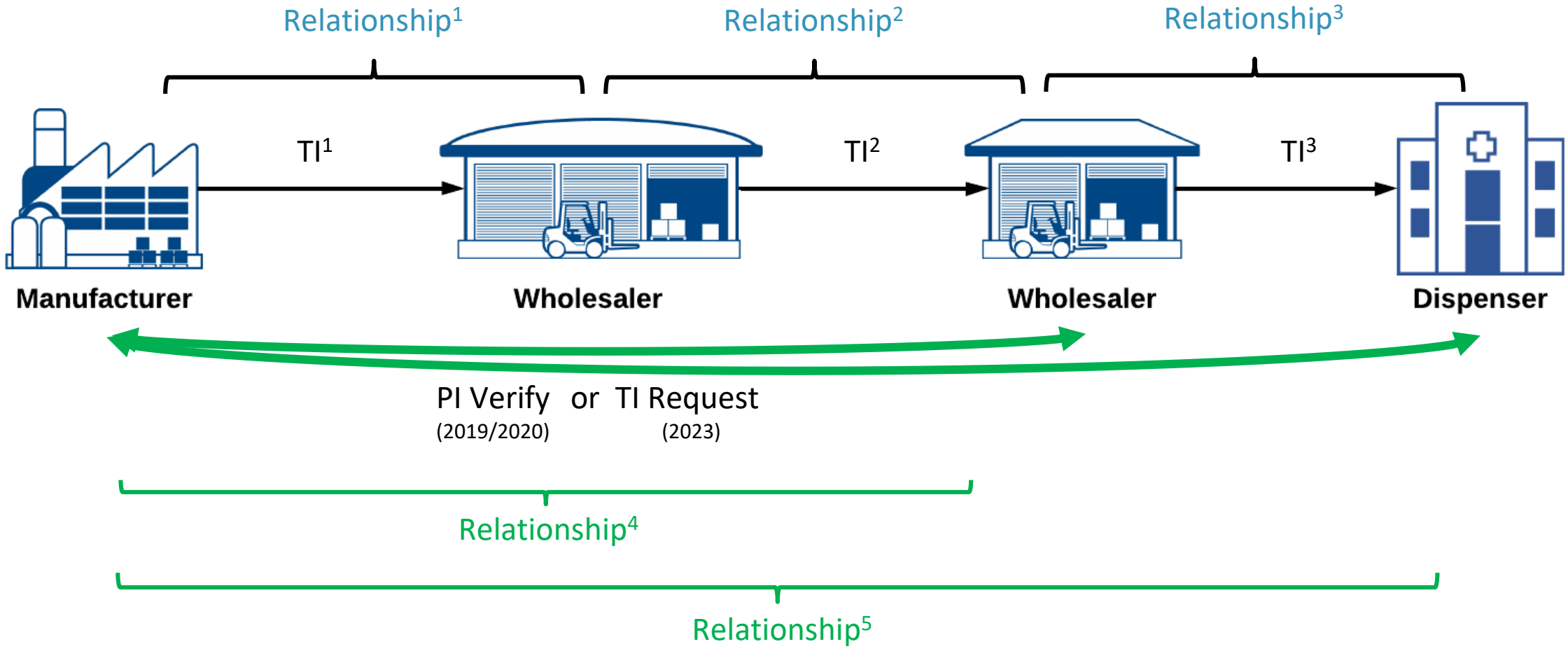
The real challenge

verifying Product Information and retrieving previous transaction information



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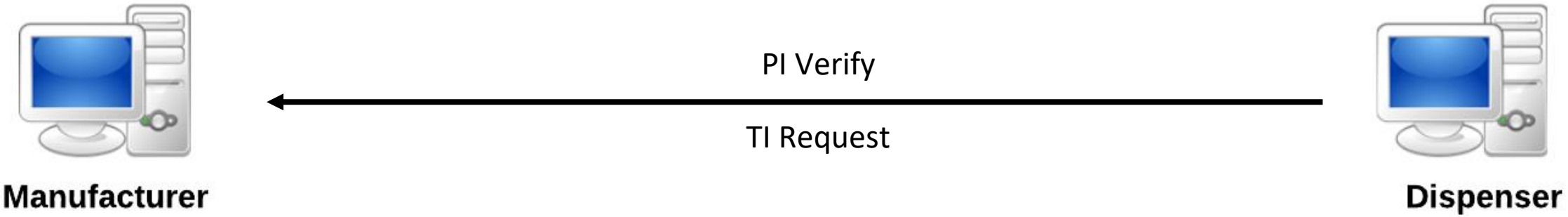
The real challenge

Establishing new digital relationships



The Manufacturer needs to Authenticate the Dispenser and authorize them to access the information.

1. **Who is asking? … Authentication**
2. **Should I respond?**
   1. **Are they a Legitimate Stakeholder?**
   2. **Have they owned the item?**

… Authorization

The Dispenser needs to Authenticate the Manufacturer.

1. **Have I connected to the real manufacturer?**

… Authentication

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We’re going to need a bigger toolbox

Digital Relationship Establishment

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Digital Relationship Establishment Framework

Manufacturer

Dispenser

Discover	Link	Authenticate	Access Policy Exchange	Authorize	Negotiate	Interact
Electronically find datasets or services	Establish an electronic connection with the system controlling access to the data or service	Both ends of the connection establish the identity of each other.	Requested system provides requesting party with their rules (policy) for access.	Requesting system provides credentials that meet the Requested party's access policy,	Both parties negotiate a value exchange in exchange for information or service access.	Access to information or a service begins.

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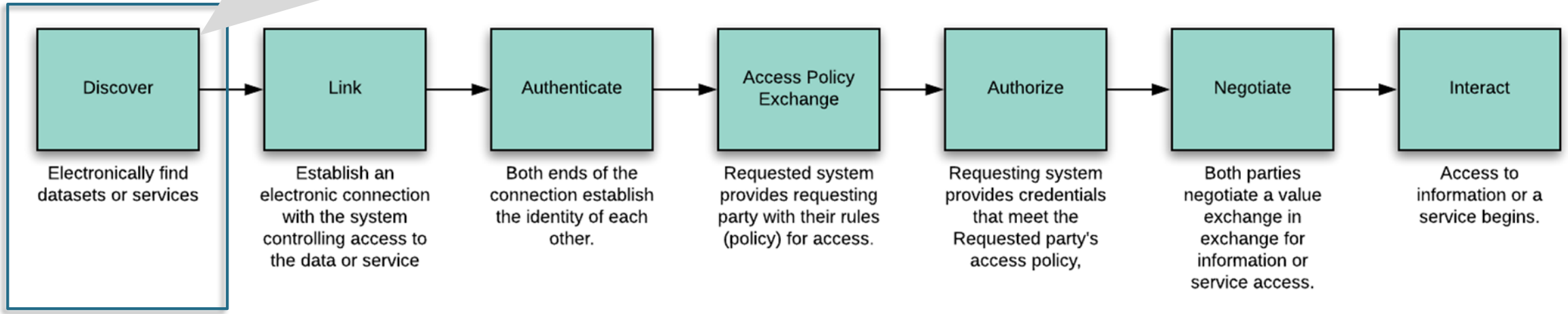
New tools Supporting
New Ways of Doing Business

GS1 Digital Link

VRS Manufacturer Directory

W3C: … URI defines a resource locator, DID

Marketplace Catalogs



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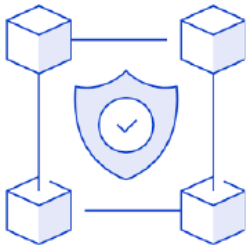
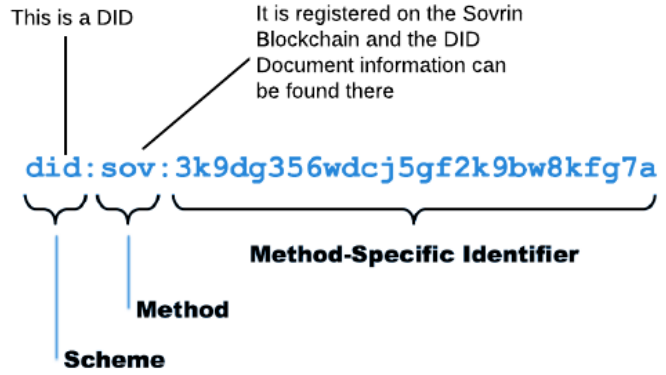
New tools Supporting
New Ways of Doing Busines

Decentralized Identifier (DID):

- Defines a unique Identifier that is verifiable
- Registered in a Blockchain
- Can be parsed to determine where information about the DID is can be found (the DID Document)





Discover	Link	Authenticate	Req			
Electronically find datasets or services	Establish an electronic connection with the system controlling access to the data or service	Both ends of the connection establish the identity of each other.	provides requesting party with their rules (policy) for access.	provides credentials that meet the Requested party's access policy,	negotiate a value exchange in exchange for information or service access.	information or a service begins.

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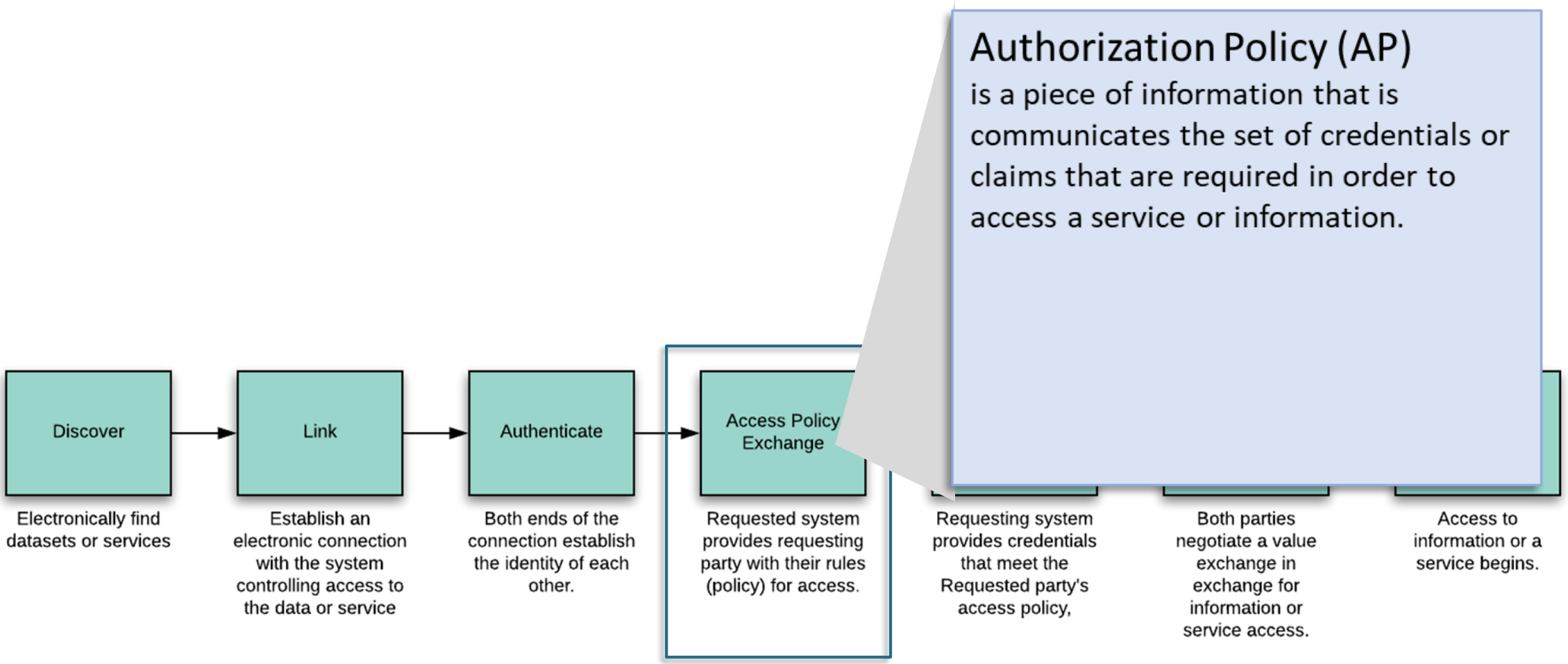
New tools Supporting
New Ways of Doing Business



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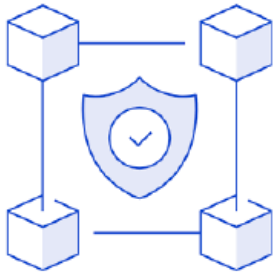
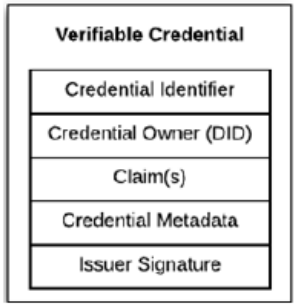
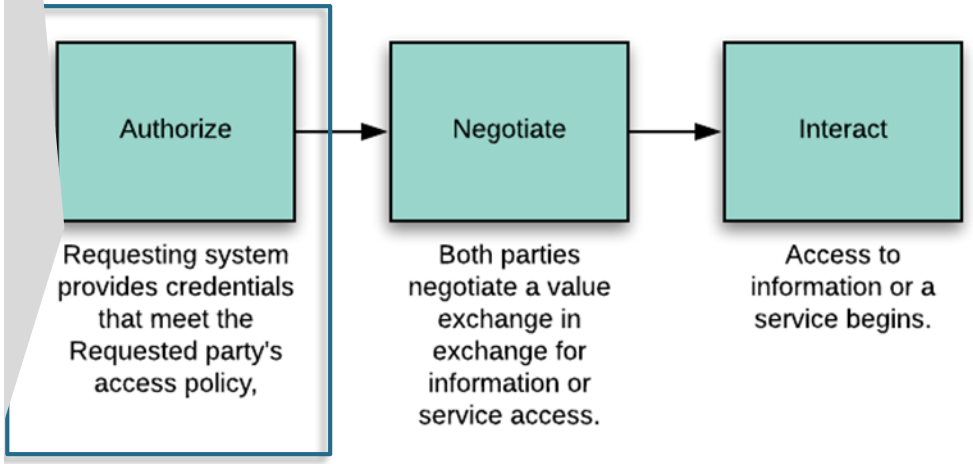
New tools Supporting
New Ways of Doing Business

Verifiable Credential:

- Information that is cryptographically trustworthy.
- Shared as a proof to a claim or set of claims made by the DID owner
- Contains a set of tamper-evident claims and metadata that cryptographically prove who issued the credential.
  - Identification and Digital signature of the Issuer.
  - Expiry Date/Time
  - Revocation mechanism (where to check if it's been revoked).
  - Public key to use for verification purposes







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How would this work?

Digital Relationship Establishment

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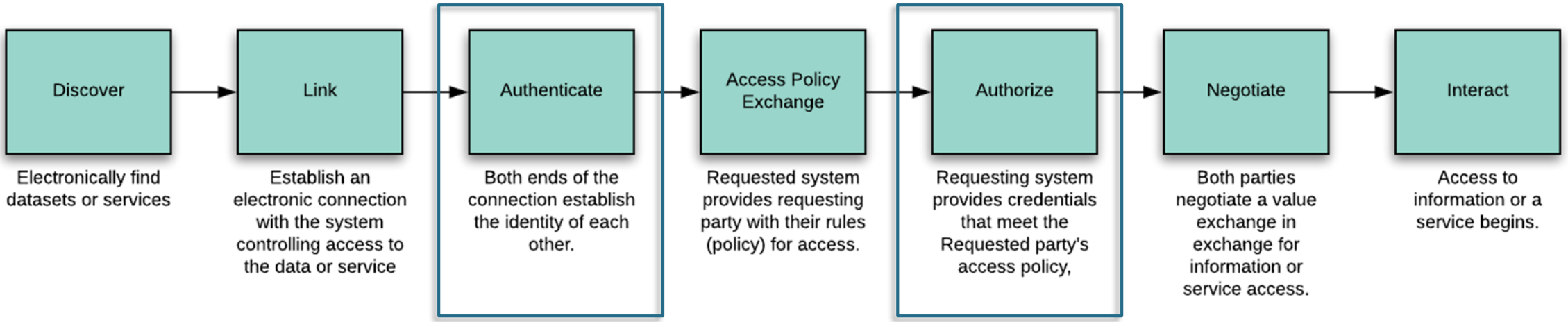
New tools Supporting
Authentication and Authorization



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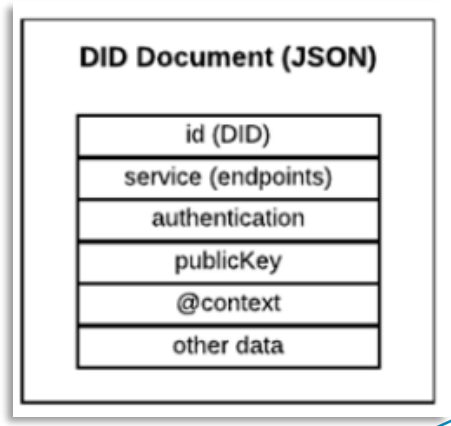
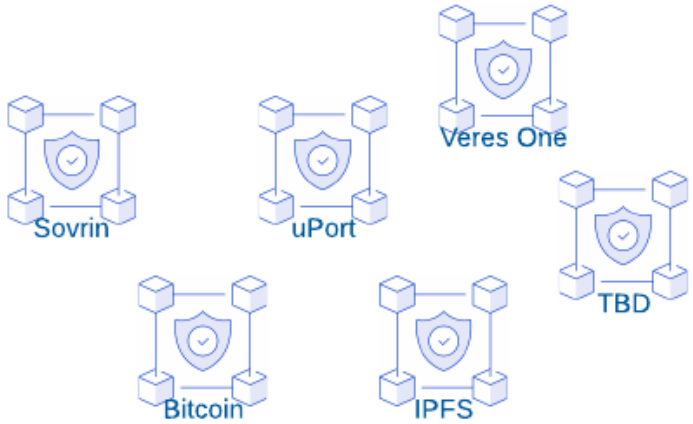
Digital Relationship Establishment Framework

Decentralized Identity





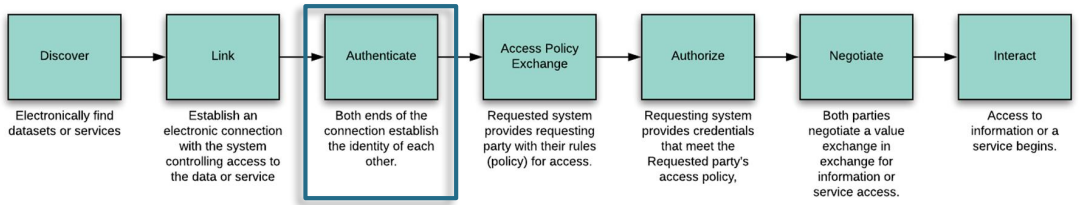
Public Blockchains

PI Verify? + `did:sov:3k9dg356wdcj5gf2k9bw8kfg7a`

Challenge

Response

Manufacturer **Dispenser**



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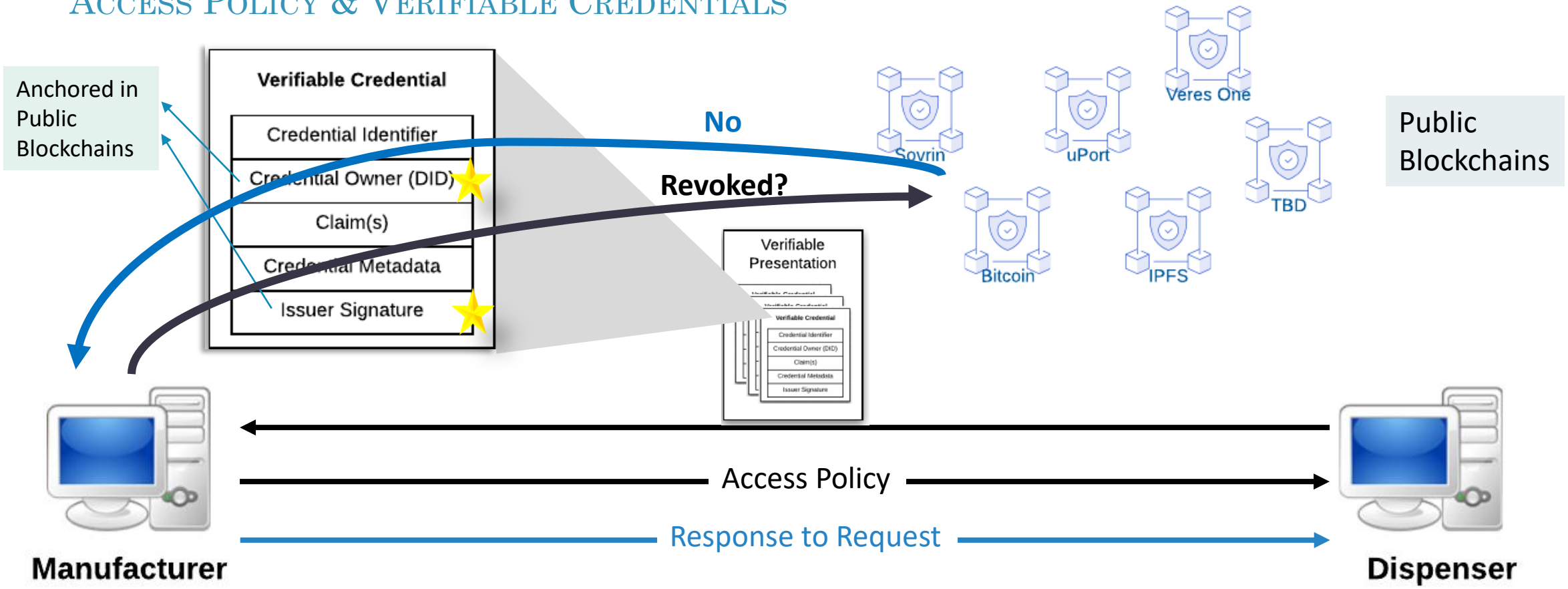
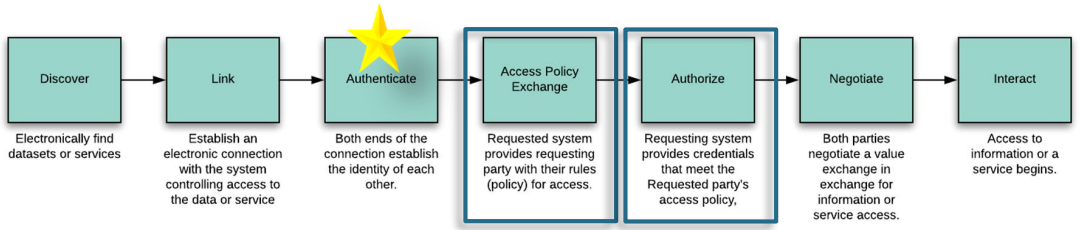
Digital Relationship Establishment Framework

Access Policy & Verifiable Credentials





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The real challenge

Establishing new digital relationships

Manufacturer

Dispenser

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How else might we use this framework?

Digital Relationship Establishment

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Digital Relationship Framework
Other Uses

DSCSA

Recall

Clinical Trials

Research Access

Medical Device Identification & Access

Government Licensing (FDA, DEA, State BoP, etc.)

Patient Identification

Prescriptions

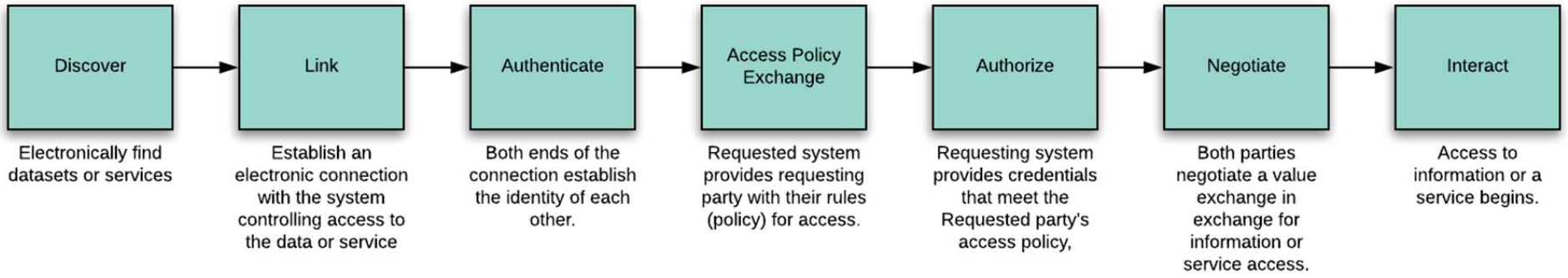
Caregiver Authentication

Patient Health Record Access

Vendor Credentialing

Medical Provider Credentialing

Employee Access Management



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Appendix

Key Concepts

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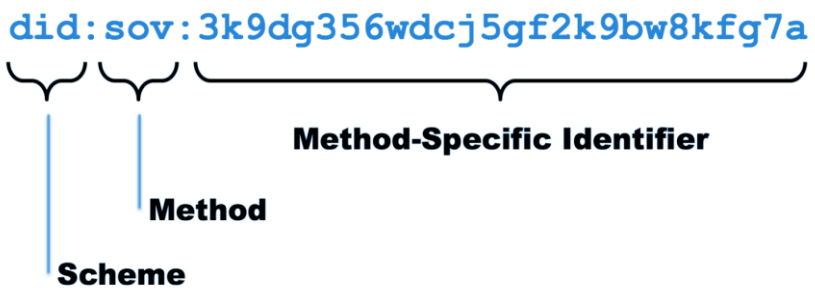
Key Concepts
Decentralized Identifier, DID Document

Decentralized Identifier (DID)

is a new type of identifier that is globally unique, resolvable with high availability, and cryptographically verifiable. DIDs are typically associated with cryptographic material, such as public keys, and service endpoints, for establishing secure communication channels.

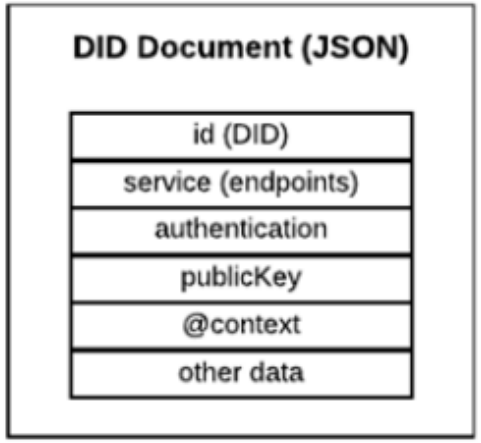


DID Document (DID Doc)

contains metadata about the DID subject (entity, person, thing). Contains minimum amount of information needed to establish a trustable connections with the DID subject.

- Public key (needed for encrypted and authenticated communication)
- Service endpoints (where the subject's API is)
- Authentication Methods
- Timestamps, proofs
- Other identifier metadata

DID document is completely public



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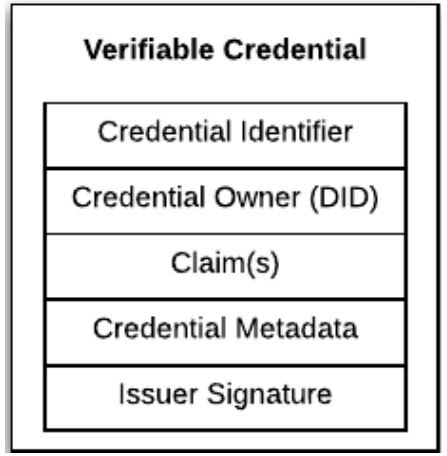
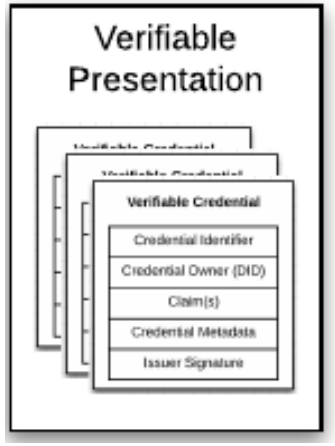
Key Concepts
Verifiable Credential, Authorization Policy

Verifiable Credential (VC)
is a piece of information that is cryptographically trustworthy. It is shared as a proof and is anchored to a public ledger by a **credential** definition and public DID written by the **credential** issuer.

Verifiable Presentation (VP)
is a piece of information that is cryptographically trustworthy. It is shared as a proof and includes claims from Verifiable Credentials.

Authorization Policy (AP)
is a piece of information that is communicates the set of credentials or claims that are required in order to access a service or information.





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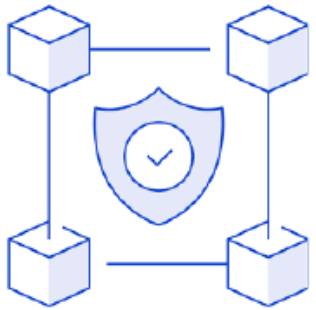
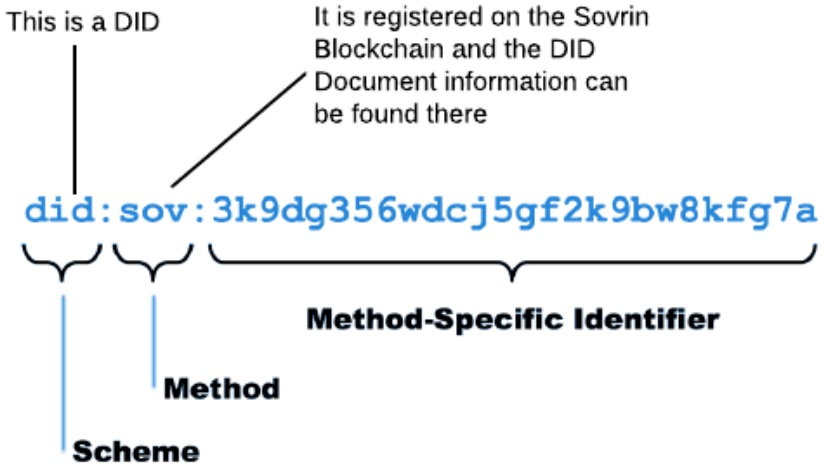
Key Concept

Decentralized Identifier (DID):

- Defines a unique Identifier that is verifiable
- Registered in a Blockchain
- Can be parsed to determine where information about the DID is can be found (the DID Document)





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Key Concept

DID Document:

- Documents verifiable information about a DID
- Set of public keys
- Set of service endpoints
- Authentication methods
- Timestamps, proofs
- Other identifier metadata

DID Document Example


```
{
 "@context": "https://w3id.org/did/v1",
 "id": "did:sov:WRfXPg8dantKVubE3HX8pw",
 "service": {
   "type": "hub",
   "serviceEndpoint":
"https://azure.microsoft.com/dif/hub/did:sov:WRfXPg8dantKVubE3H"
 },
 "publicKey": [
   {
     "id": "did:sov:WRfXPg8dantKVubE3HX8pw#key-1",
     "type": "Ed25519VerificationKey2018",
     "publicKeyBase58":
"H3C2AVvLMv6gmMNam3uVAjZpfkcJCwDmqPV"
   }
 ],
 "authentication": {
   "type": "Ed25519SignatureAuthentication2018",
   "publicKey": [
     "did:sov:WRfXPg8dantKVubE3HX8pw#key-1"
   ]
 }
}
```


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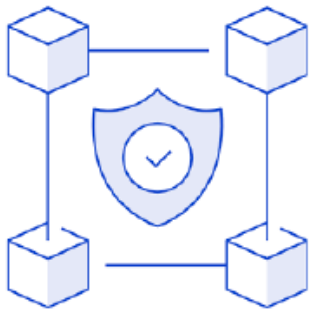
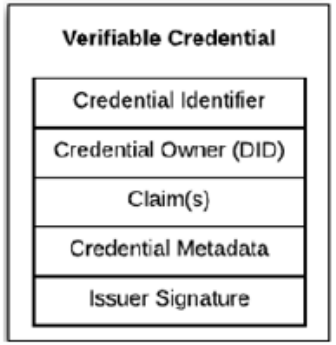
Key Concept

Verifiable Credential:

- Information that is cryptographically trustworthy.
- Shared as a proof to a claim or set of claims made by the DID owner
- Contains a set of tamper-evident claims and metadata that cryptographically prove who issued the credential.
  - Identification and Digital signature of the Issuer.
  - Expiry Date/Time
  - Revocation mechanism (where to check if it's been revoked).
  - Public key to use for verification purposes





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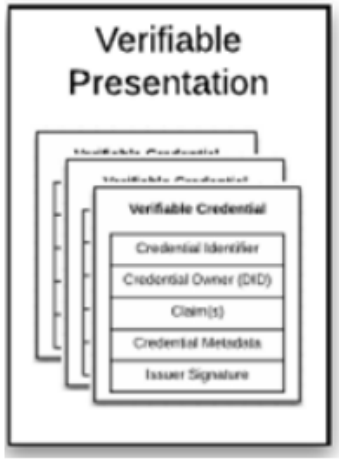
Key Concept

Verifiable Presentation:

is a piece of information that is cryptographically trustworthy. It is shared as a proof and includes claims from Verifiable Credentials.



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Report Out & Action Steps

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