SPARED CRN

Clinical Working Groups and Informatics Working Group Coordination: Standard Data Capture

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Agenda

1. Leveraging Women's Health Technology Informatics
2. Coordinating Clinical and Informatics Working Groups
    a) Today's focus: Coordinating and harmonization and standardization of Core Data Elements (CDEs) identified by Clinical Working Groups
    b) Review of Template to help exchange CDEs and information between Clinical Working Groups and Informatics Working Group
3. UDI – Common data element for device identification
    a) Integration in real world
    b) Challenges in UDI data
4. Next Steps?

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Leveraging Women's Health Technology (WHT) Informatics Projects

- **National Institutes of Health (NIH)/National Library of Medicine (NLM)**
  - Provide guidance and best practices for data collection, reuse of high quality CDEs and forms, and tooling to support the reuse and creation of CDEs and forms.
  - Provide curation services and copyright verification services for the minimum core set of data elements and forms to be used by the identified registries.
  - Leverage NLM clinical data standards and clinical work.
- **Food and Drug Administration (FDA) Informatics**
  - Project Management over the PCORTF Informatics team.
  - Model the PCORTF WHT project requirements (including the device's UDI) into data exchange messages (e.g. HL7 FHIR).
  - Identify and resolve data quality issues with GUDID entries for WHT-CRN devices.
  - Enable interface with the GUDID to enhance the CRN tools.
- **The Office of the National Coordinator for Health Information Technology (ONC)**
  - Leverage existing work being done in the research community and utilize national health standards to test the building of an infrastructure examining women's health technologies.
  - Recruit pilot participants and propose an analytical framework to address feasibility issues for each of the identified registries.

General Objectives for CRNs

- Help establish a strategically coordinated registry network (CRN) and develop tools to facilitate collection of data within the existing and new registries by leveraging clinical care data

- Demonstrate that a common set of data elements can be used for improving device evaluation by providing more precise ways to:
  - Evaluate the effectiveness, quality of life and safety associated with differing treatment options
  - Assess the effectiveness and quality of life associated with varying treatment options
  - Provide a framework for clinical studies to be conducted within the registry, including industry-sponsored studies for pre-market and post-market regulatory activities
  - Allow healthcare providers to track surgeon volume, patient outcomes, and quality measures for quality improvement activities and fulfill upcoming Centers for Medicaid and Medicare Services (CMS), Physician Quality and Reporting Systems (PQRS) and maintenance of certification requirements

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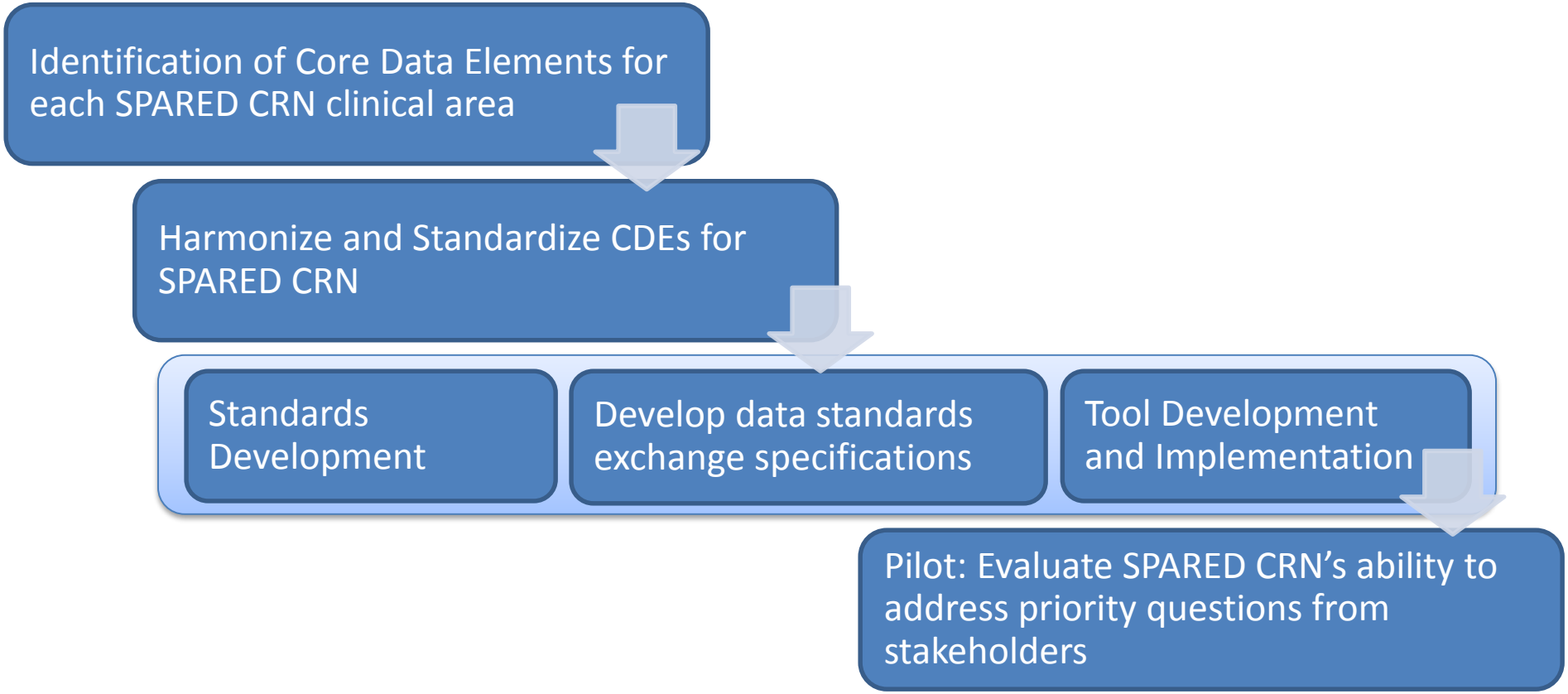
Clinical/Informatics Activities (High-level)



Clinical/Informatics Activities (High-level)

Identification of Core Data Elements for each SPARED CRN clinical area

Harmonize and Standardize CDEs for SPARED CRN

Today's Focus:

Coordination between Clinical Working Groups (CWG) and the Informatics Working Group (IWG) on harmonizing and standardizing the CDEs identified by CWG

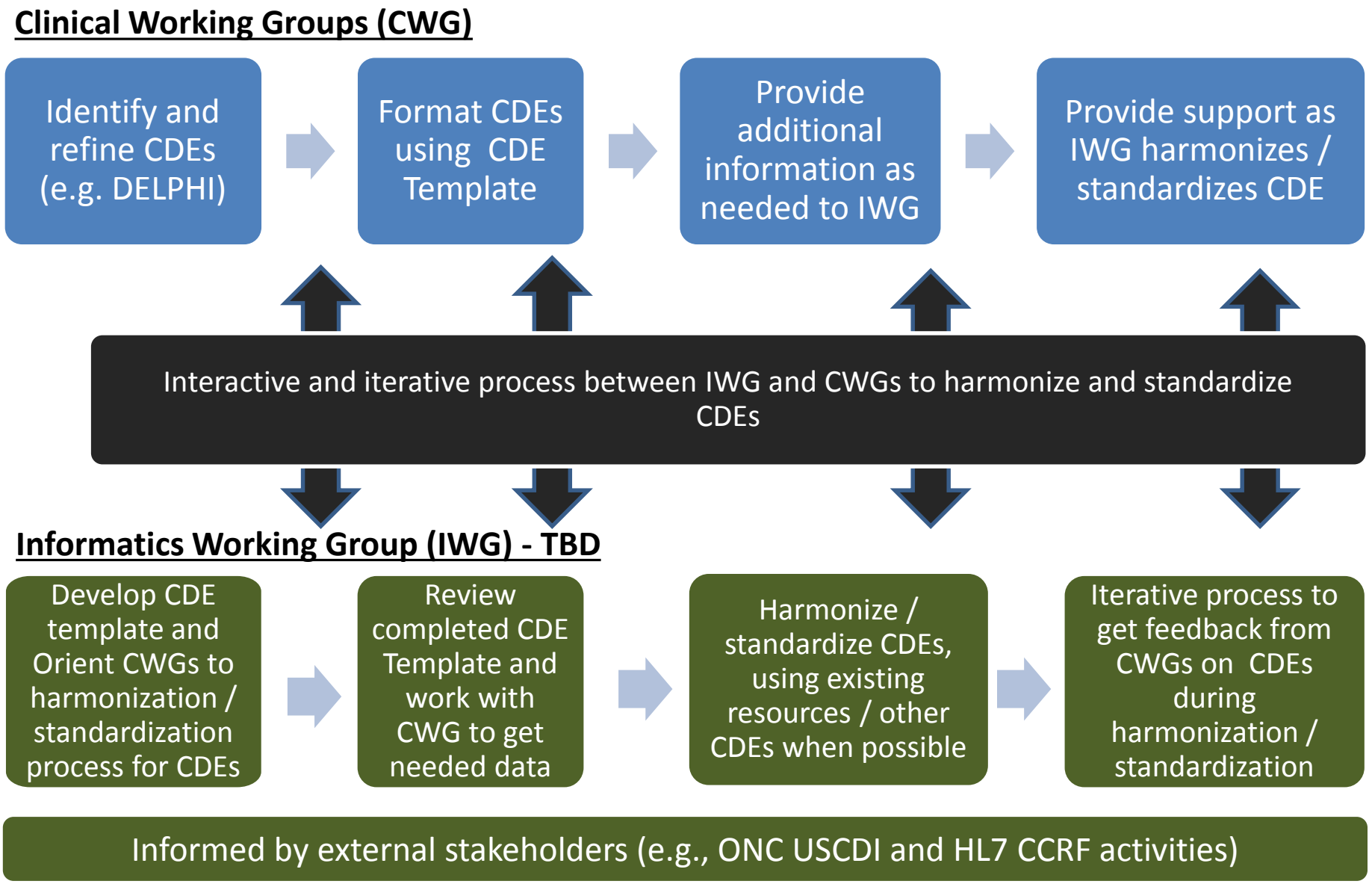
Standards Development

Develop data standards exchange specifications

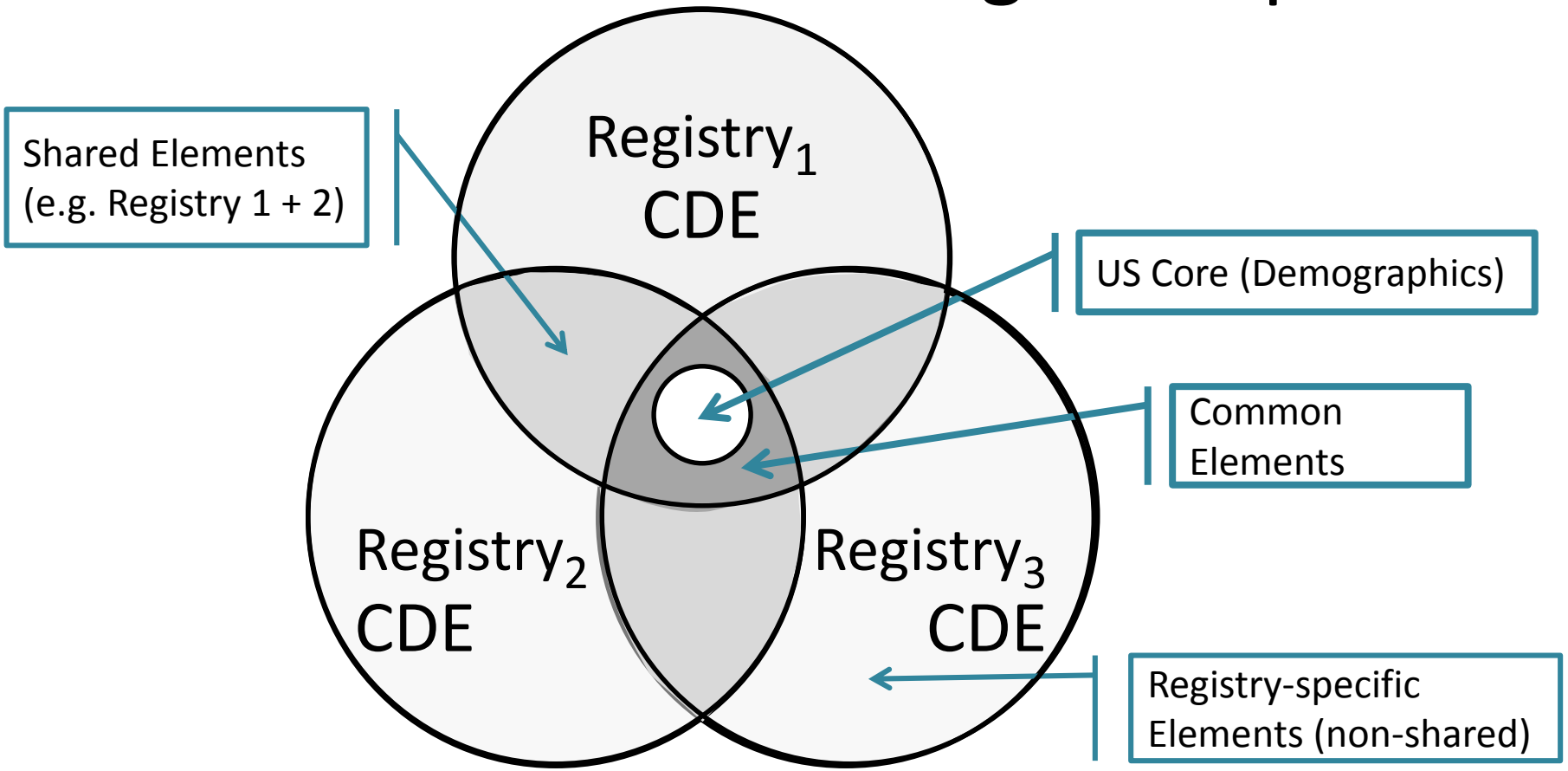
Tool Development and Implementation

Pilot: Evaluate SPARED CRN's ability to address priority questions from stakeholders

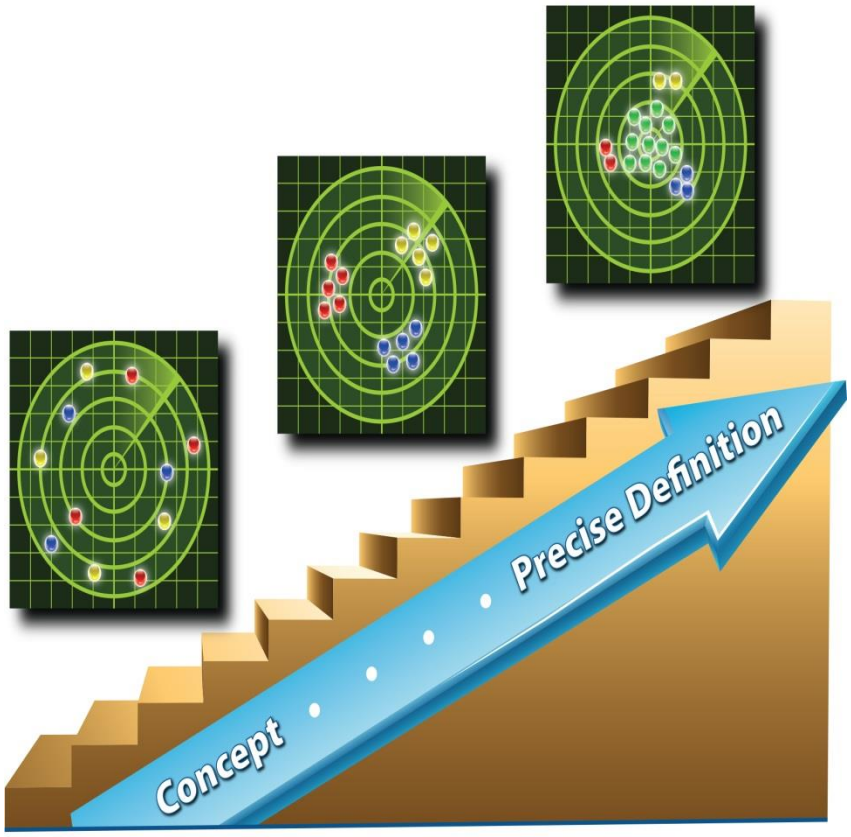
Overview of Key Steps for CRN-CDE Harmonization and Standardization



Review of CDE Template
CRN CDE Collection – Target Endpoint



Objective – Move from Concept to Precise Definitions



- Moving from concept to precisely-defined CDEs has many moving parts and interactive steps
  - Discovery
  - Local Agreement
  - Global Harmonization
- Keep it simple to start
  - Identify and organize the concepts within generic domains (i.e. shared across clinical working groups)
  - Capture minimum sets of required elements and refine each iteration
- Grow the complexity
  - Increase precision of variable definitions
  - Identify clinical measures
  - Develop technical representations for variables (e.g. data format, code values/value sets
- Deliver a harmonized set of CDEs with respect for the unique needs of the individual domains

Objective – Review Data Collection Process

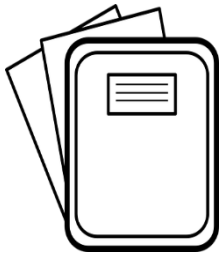
- Data Collection Best Practices
  - How is the Data Collected
  - What is the Sequence the Data is Collected
  - How frequently will you ask the same question, i.e. pre- and post-operative
- Develop a Case Report Form then specify further
  - Ask questions to verify the definitions, represent and describe the medical knowledge – see the *Creating Biomedical and Clinical Data Elements and Forms Metadata handout*

Data Planning	Assessments, Instruments, Surveys	Variables

• Be exact and discrete
  • BP -> systolic (mmHG) + diastolic BP (mmHG)
• Include confounding factors
• Store raw data fields rather than calculated
• Use terminology from API or NLM terminology resources to ensure accuracy and validity
• Minimize open-ended free text entry
	• Use full instrument name, include abbreviations
	• Provide rules for display or skip logic
	• Be aware of copyright or other conditions for use (and reuse)
		• Review for best “data type”
		• Code categorical variables
		  • M=Male, F=Female, 1=Female, 0=Male
		• Provide ranges for numeric elements
		• Allow for missing data
		  • “Flavors of null”
		  • Refused, Missing, Don’t know
		• Instructions for calculated fields

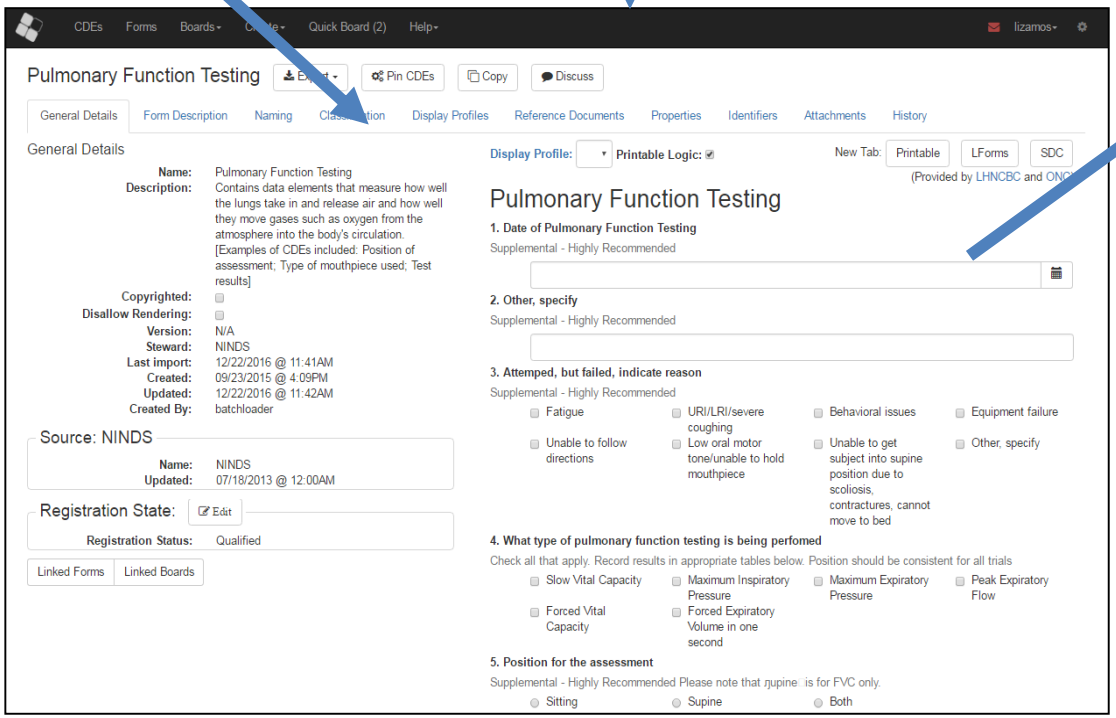
Paper CRF to Electronically Exchangeable Form

Collection: Case Report Forms



Collection: CDE Spreadsheet Template

Variable	Description
Unique ID	*Assign a unique ID to each data element (System Assigned)*
Technical Short Name *	*This is an abbreviated name for the data element typically for database purposes.*



Export in machine-readable format


```
{
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  "isCopyrighted": false,
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    }
  ],
  "displayProfiles": [],
  "classification": [ … ], // 1 item
  "formElements": [
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            "required": false,
            "uoms": [],
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              "name": "Pulmonary function test date and time",
              "version": "3",
              "ids": [
                {
```

CDE Spreadsheet Template

Variable	Description
Unique ID	*Assign a unique ID to each data element (System Assigned)*
Technical Short Name *	*This is an abbreviated name for the data element typically for database purposes.*
Data Element Short Name *	*Short (familiar) name for the concept.*
Data Element Label * (Long Name/Question Text)	*The full name for the concept or the Question text. This should be recognizable to both a business and technical person.*
Data Element Definition *	*A short description of the data element and its concept. This should align to other sources to ensure interoperability and include synonyms or any alternate names used for the same concept (e.g., first and last name would be synonyms of given and family name (respectively)).*
Data Type *	*How the data should be collected (e.g., code, numeric, alphanumeric, Boolean, value set)*
Value parts + (UOM, Range, Limits, Numerical Precision, Conditional Logic)	*If a value is structured and has multiple parts, they should be identified as individual attributes* *o E.g., measurements have a value and unit of measure (e.g., 5 cm)* *o E.g., ranges have the potential for an upper and lower value and unit of measure (e.g., temperature of 96F – 100F)*
Value set (Value) +	*List each value in the value set (part of a Value:Meaning pair, see element below)*
Definitions of the elements of the value set (Value Meaning)+	*Provide a definition for each value in the value set.*
Code System +	*For codified values, do we know of a code system that could be used*
Reference source * (if known) (Reference Document)	*Provide a reference for the value set, especially if it is different than the code system. In some cases, there will not be an associated code system for the value set)*
Classification +	*Organizing principle, Delphi priority. Where does it fit? How are you thinking about it?*
Frequency of Collection	*If this data element is collected in set interval and/or a particular frequency - please note it here.*
Example Data	*Examples are great to verify form and intent. Include whenever possible.*

CDE Example Data #1

Variable	Example	Example
Unique ID		
Technical Short Name *		
Data Element Short Name *	Sex	Date of birth
Data Element Label * (Long Name/Question Text)	Administrative Gender (HL7 V3)	Birth date
Data Element Definition *	The patient's sex, assigned at birth	The date the patient was born
Data Type *	Value Set	Date
Value parts + (UOM, Range, Limits, Numerical Precision, Conditional Logic)		MM/DD/YYYY
Value set (Value) +	M, F, UN	
Definitions of the elements of the value set (Value Meaning)+	Male, Female, Undifferentiated	
Code System +	VSAC (2.16.840.1.113883.1.11.1, version 20171120)	LOINC (21112-8)
Reference source * (if known) (Reference Document)	The standard specified in § 170.207(n)(1) - Birth sex must be coded in accordance with HL7 version 3 (V3) Standard.	
Classification +	Demographics	Demographics
Frequency of Collection		
Example Data		

CDE Example Data #2

Variable	Example
Unique ID	
Technical Short Name *	
Data Element Short Name *	Race
Data Element Label * (Long Name/Question Text)	Race
Data Element Definition *	Race OMB.1997
Data Type *	Value Set
Value parts + (UOM, Range, Limits, Numerical Precision, Conditional Logic)	
Value set (Value) +	Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, Asian, Black or African American, White, Other Race
Definitions of the elements of the value set (Value Meaning)+	Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, Asian, Black or African American, White, Other Race
Code System +	VSAC (2.16.840.1.114222.4.11.836, version 20161109)
Reference source * (if known) (Reference Document)	Race OMB.1997 The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and the standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).
Classification +	Demographics
Frequency of Collection	

CDE Example Data #3

Variable	Example
Unique ID	
Technical Short Name *	
Data Element Short Name *	Ethnicity
Data Element Label * (Long Name/Question Text)	Ethnicity
Data Element Definition *	Ethnicity OMB.1997
Data Type *	Value Set
Value parts + (UOM, Range, Limits, Numerical Precision, Conditional Logic)	
Value set (Value) +	Hispanic or Latino, Not Hispanic or Latino
Definitions of the elements of the value set (Value Meaning)+	Hispanic or Latino, Not Hispanic or Latino
Code System +	VSAC (2.16.840.1.114222.4.11.837, version 20161109)
Reference source * (if known) (Reference Document)	Ethnicity OMB.1997 The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and the standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).
Classification +	Demographics
Frequency of Collection	
Example Data	

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Frequency of Collection	*If this data element is collected in set interval and/or a particular frequency - please note it here.*
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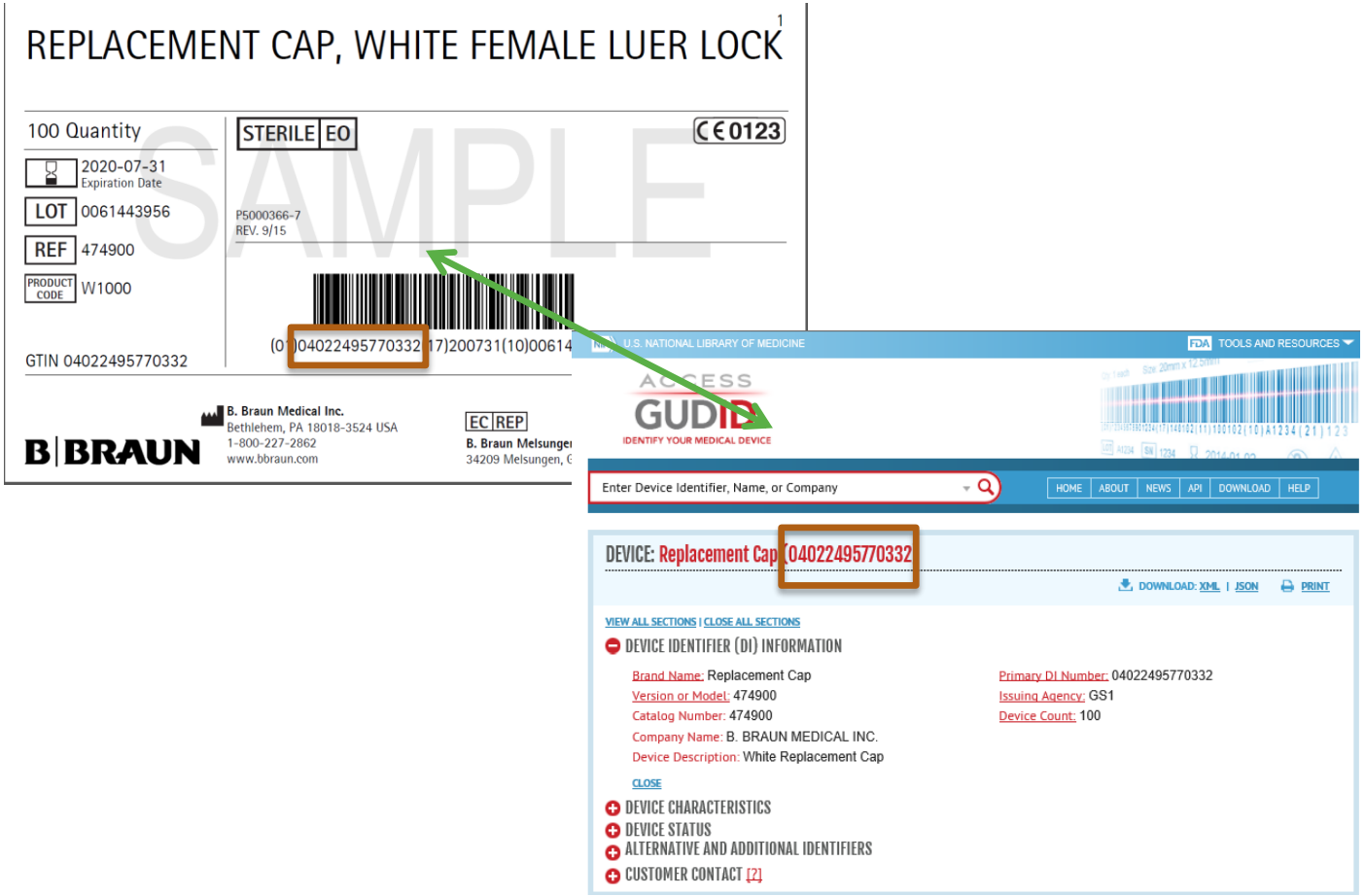
UDI: CDEs for Device Identification



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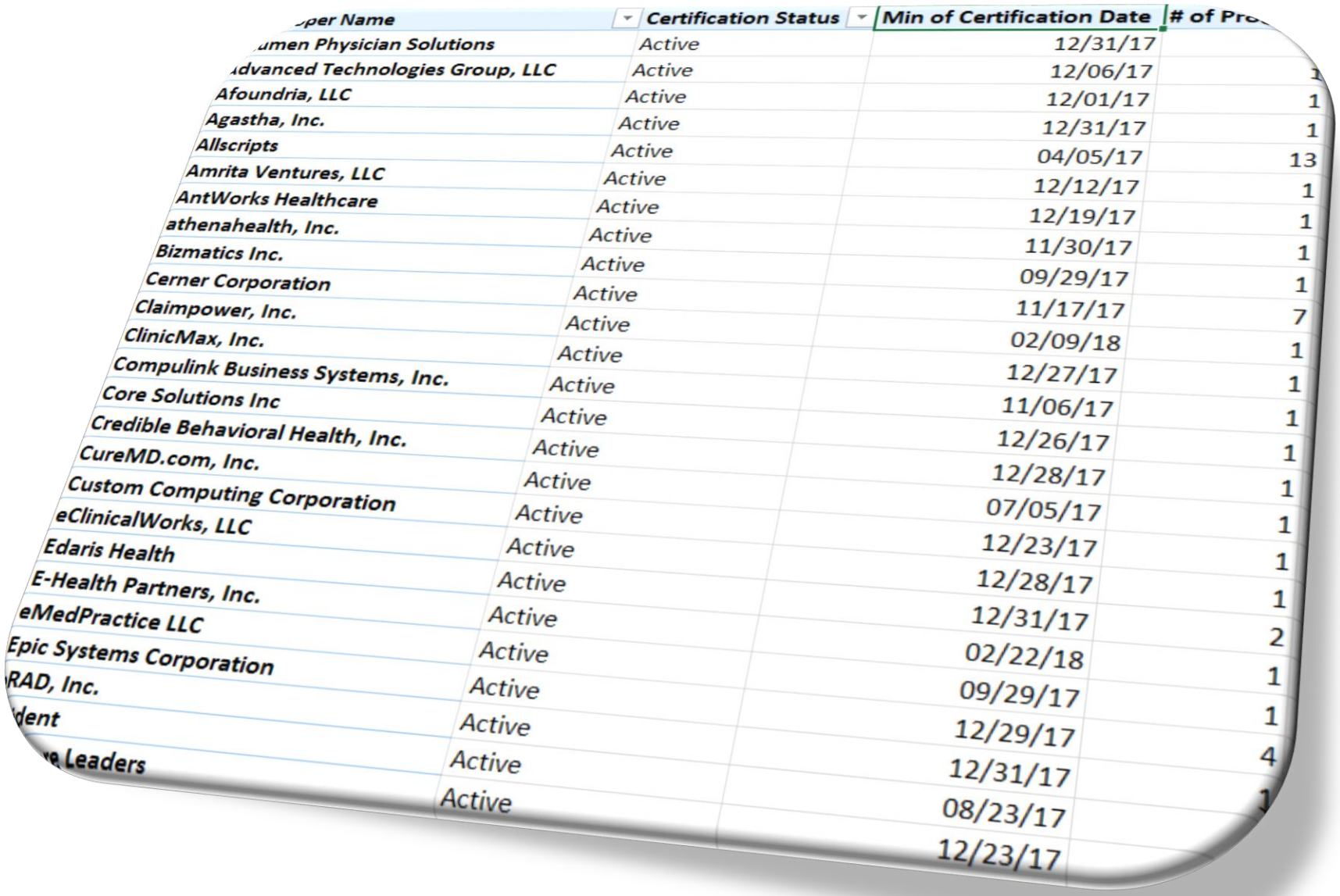
UDI capture is available in 75 EHRs



...per Name	Certification Status	Min of Certification Date	# of Pr...
...umen Physician Solutions	Active	12/31/17	
...dvanced Technologies Group, LLC	Active	12/06/17	1
Afoundria, LLC	Active	12/01/17	1
Agastha, Inc.	Active	12/31/17	1
Allscripts	Active	04/05/17	13
Amrita Ventures, LLC	Active	12/12/17	1
AntWorks Healthcare	Active	12/19/17	1
athenahealth, Inc.	Active	11/30/17	1
Bizmatics Inc.	Active	09/29/17	1
Cerner Corporation	Active	11/17/17	7
Claimpower, Inc.	Active	02/09/18	1
ClinicMax, Inc.	Active	12/27/17	1
Compulink Business Systems, Inc.	Active	11/06/17	1
Core Solutions Inc	Active	12/26/17	1
Credible Behavioral Health, Inc.	Active	12/28/17	1
CureMD.com, Inc.	Active	07/05/17	1
Custom Computing Corporation	Active	12/23/17	1
eClinicalWorks, LLC	Active	12/28/17	1
Edaris Health	Active	12/31/17	2
E-Health Partners, Inc.	Active	02/22/18	1
eMedPractice LLC	Active	09/29/17	1
Epic Systems Corporation	Active	12/29/17	4
RAD, Inc.	Active	12/31/17	1
dent	Active	08/23/17	
e Leaders	Active	12/23/17	

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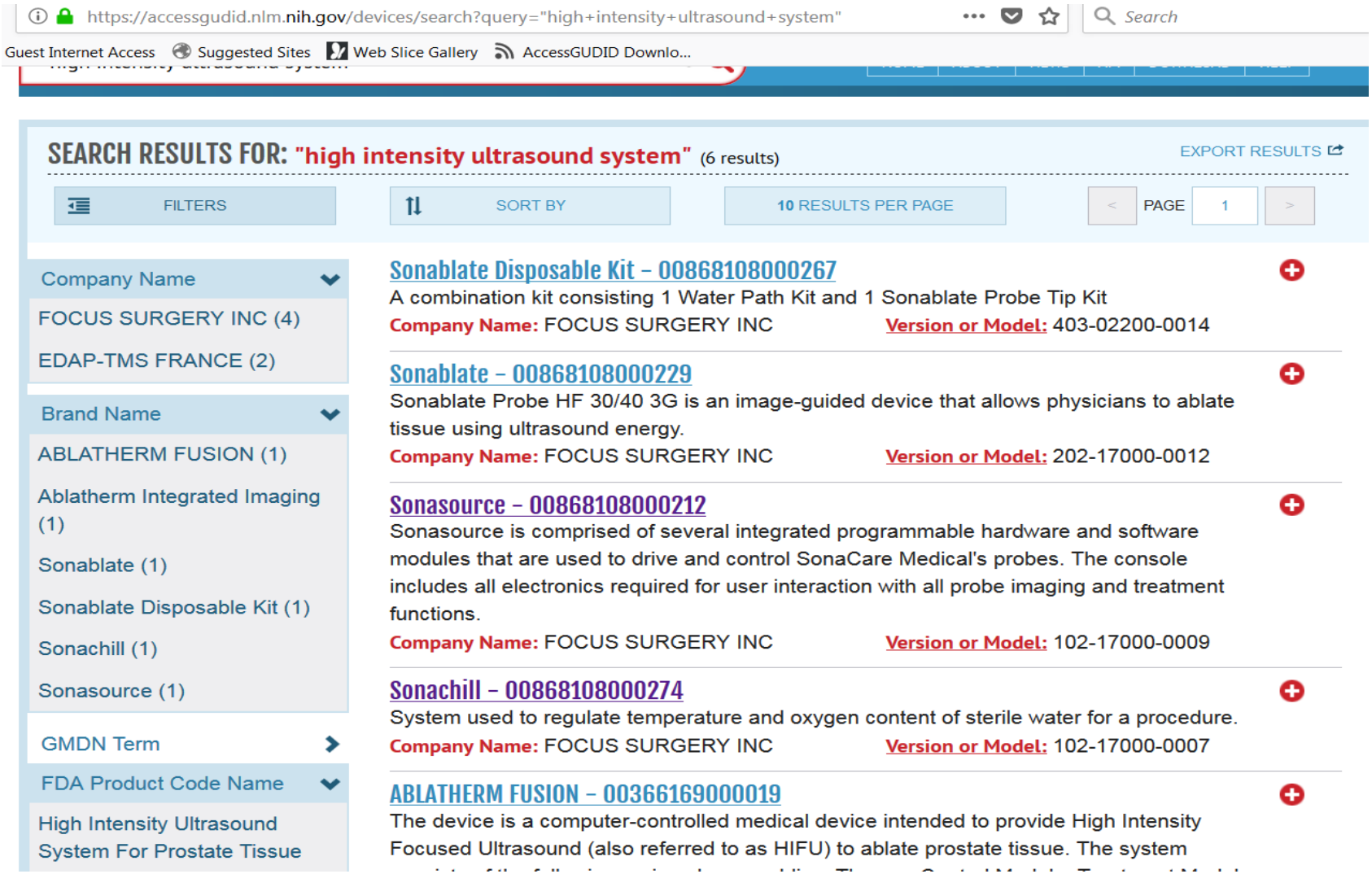
SPARED data in AccessGUDID



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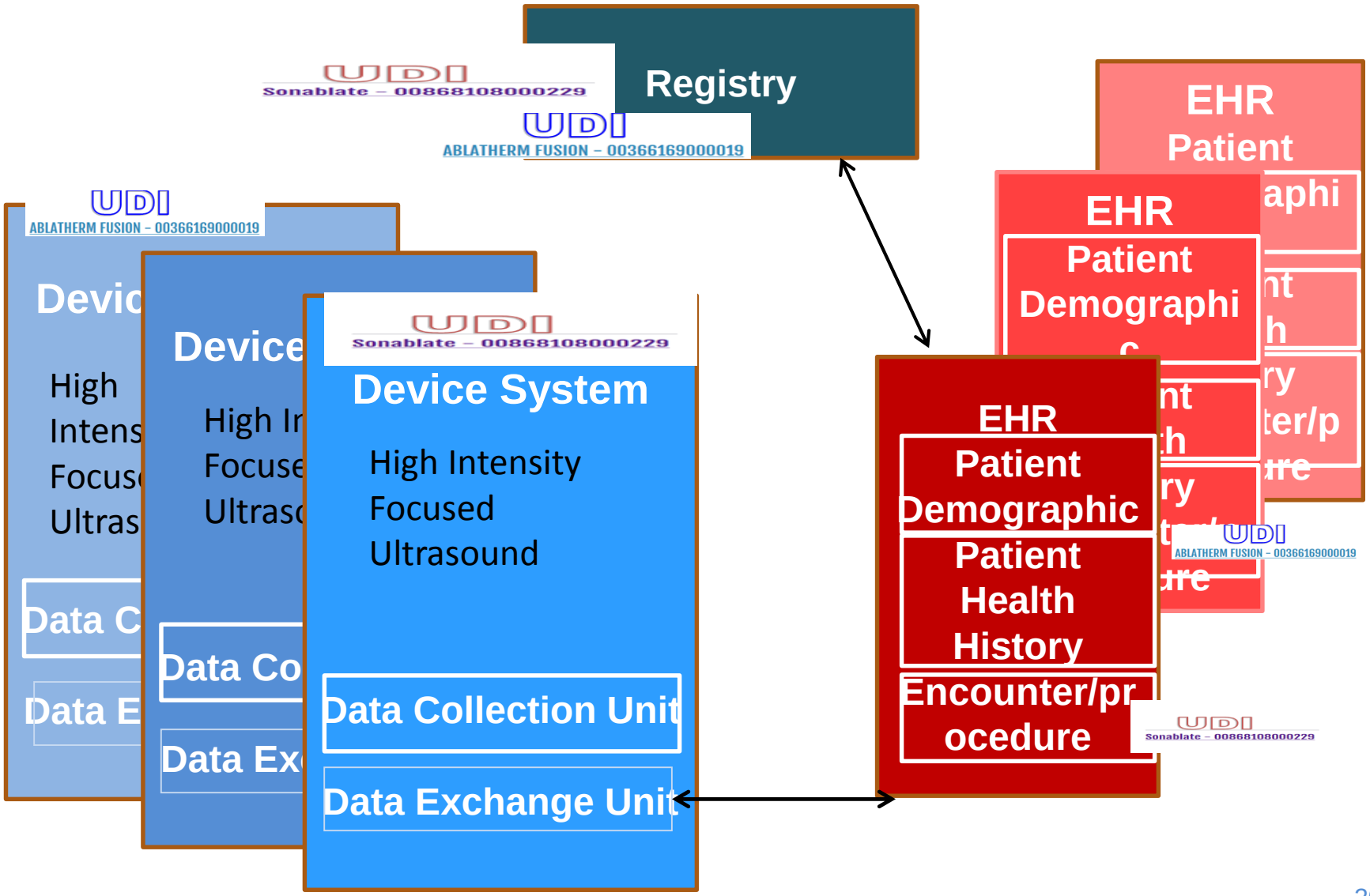
Standard Data Capture



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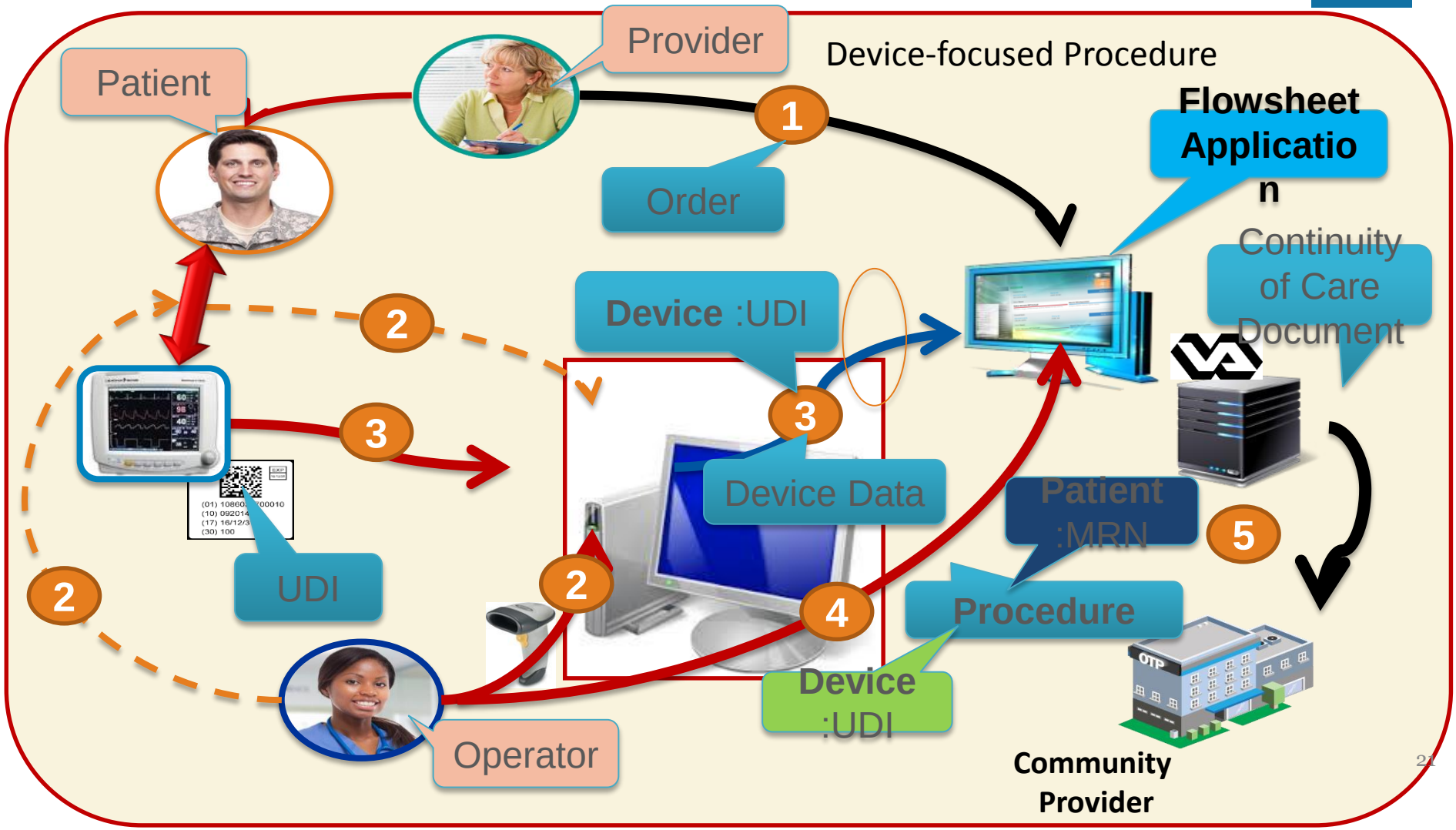
Device-focused Procedure
Patient
Provider
1
Order
Flowsheet Application
Continuity of Care Document
2
Device :UDI
3
Device Data
UDI
2
2
4
Patient :MRN
5
Procedure
Device :UDI
Operator
Community Provider

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UDI is in Registries

Enter data ONCE to support data capture and device

WL GORE

Vascular Quality Initiative

DEVICE: GORE VIABAHN Endoprosthesis (00733132614394)

DOWNLOAD: XML | JSON

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: GORE VIABAHN Endoprosthesis
Version or Model: VBC050502
Catalog Number:
Company Name: W. L. Gore & Associates, Inc.
Device Description: No description.

Primary DI Number: 00733132614394
Issuing Agency: GS1
Device Count: 1

Treatment Type: Stent Graft
Product Number or DI: VBC
Manufacturer
Type
GUDID Diameter
GUDID Length

VBC050202 DI:00733132614387
VBC050502 DI:00733132614394
VBC051002 DI:00733132614400
VBC051502 DI:00733132614417
VBC060202 DI:00733132614424
VBC060501 DI:00733132614431
VBC060502 DI:00733132614448

Device 1

Treatment Type: Stent Graft
Product Number or DI: VBC050502 DI:00733132614394
Manufacturer: W. L. Gore & Associates, Inc.
Type: GORE VIABAHN Endoprosthesis
GUDID Diameter: 5 Millimeter
GUDID Length: 5 Centimeter

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Shared Responsibility

Go beyond compliance with UDI regulation

Reduce gap between what UDI **users** need and what **manufacturers/third parties submit and what FDA monitors in AccessGUDID.**

- Improve the scannability of UDI at point of care OR inclusion of UDI as part of data collected/provided from a medical device
- Improve AccessGUDID as a public good for Real World Data by reducing access barriers
- Improve device identification data submitted to support regulatory decisions made using real world evidence

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2018 Medical Device Safety Action Plan

Protecting Patients, Promoting Public Health

FDA

UDI

- Key component of Medical Device Safety Net Program
- Standard identifier to be used across Total Product Life Cycle
- Essential to National Evaluation System for health Technology to facilitate
- Facilitates active surveillance and decision making by:
  - Identifying the specific device used in the care of a patient
  - Providing opportunity for cost savings coupled with other benefits, such as near real-time access to high quality data to support decision making and access to better evidence

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Global Commitment

International Regulators Forum UDI Application Guide Working Group – formed in November 2017

Purpose: To promote a globally harmonized approach to the application of a UDI system. UDI as a global standard for device identification

Australia	Brazil	Canada	China	EU
Japan	Russian Federation	Singapore	South Korea	US
GMTA	DITTA	WHO		

UDI Regulatory Work

WG Regulatory Member

Manufacturer Rep

Observer

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Next Steps