Global GS1 Healthcare Conference
Bethesda, MD, 6-8 April 2011

How to Model UDI GHTF Data Elements in HL7

(HL7 SPL Release 5)

Todd Cooper
Co-Chair, HL7 Health Care Devices WG

Background

Todd Cooper

- Co-Chair, HL7 Health Care Devices WG
- Convenor, ISO TC215 WG7 Health Informatics – Devices
- Chair, IEEE 11073 General Committee
- Board, Integrating the Healthcare Enterprise (IHE) International
- Co-Founder, IHE Patient Care Device (PCD) Domain
- Co-Chair, ISO/IEC JWG7 “80001” Standard
- Principal, 80001*Experts*, LLC

❖ ***Medical Device Informatics & Interoperability***

❖ At heart … a ***software engineer*** … medical device guy … standards dude!

❖ From San Diego … “***America’s Finest City!***”

Acronymosity

Global Harmonization Task Force

Working Towards Harmonization in Medical Device Regulation

www.GHTF.org

UDI — **Unique Device Identification**

Health Level Seven International

www.HL7.org

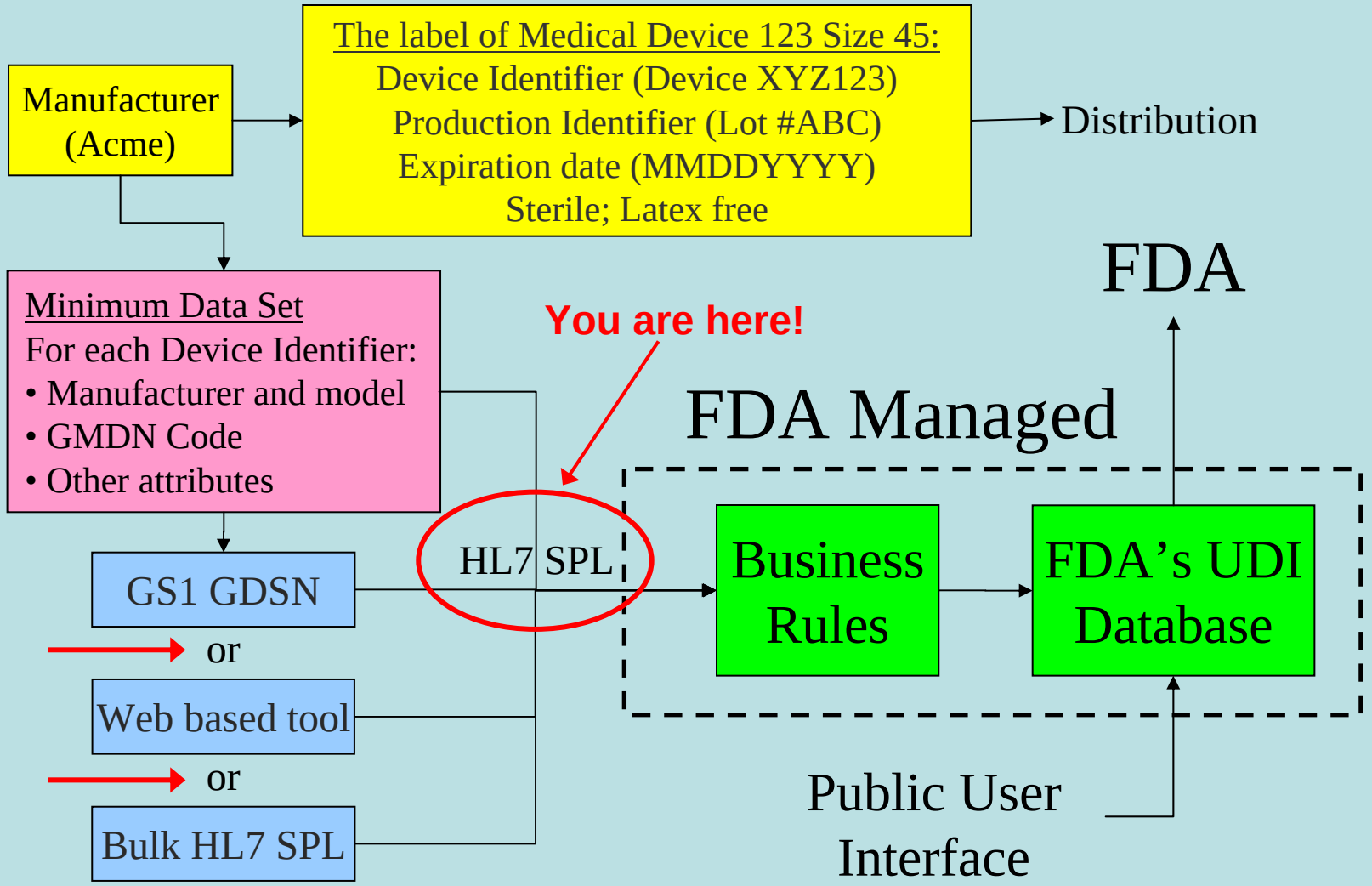
SPL — **HL7 Structured Product Labeling**

CPM — **HL7 Common Product Model**

Integrating the Healthcare Enterprise

www.IHE.net

UDI – The Big Picture



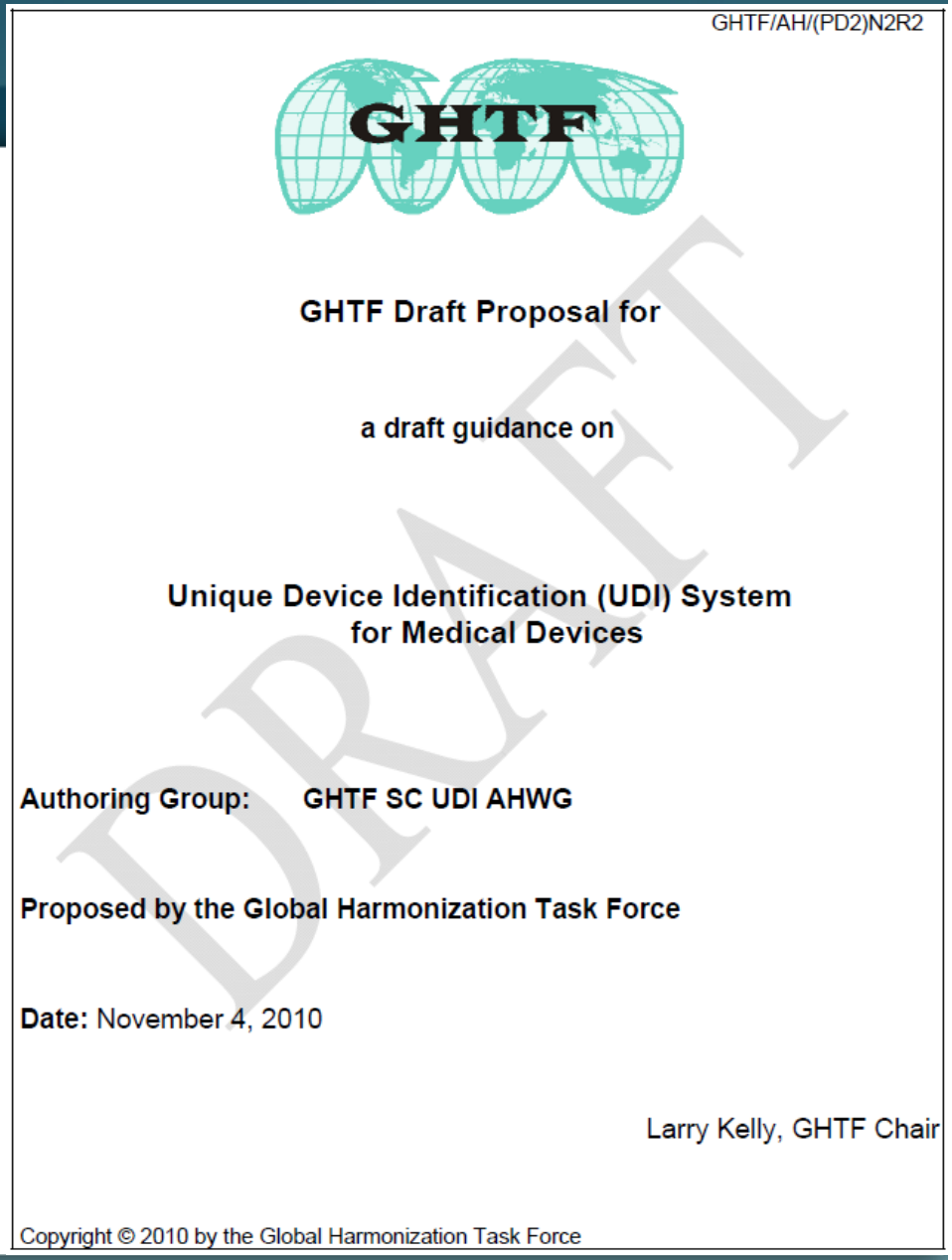
(From Jay Crowley, FDA CDRH, 2011.04.06)

GHTF UDI Data Elements

- ✓ *Abstract* **UDI** *data elements* **defined in the GHTF draft guidance document @**

  www.ghtf.org/adwg/ahwg-proposed.htm.

  Comments due by 2011.04.30!
- ✓ **Abstract data model elements are mapped to international standardized** *interchange formats*, **such as HL7 SPL** ***/*** **CPM**
- ✓ **Implementation** *technology independent*!



GHTF/AH/(PD2)N2R2

GHTF

GHTF Draft Proposal for

a draft guidance on

Unique Device Identification (UDI) System for Medical Devices

Authoring Group: **GHTF SC UDI AHWG**

Proposed by the Global Harmonization Task Force

Date: November 4, 2010

Larry Kelly, GHTF Chair

DRAFT

GHTF UDI Data Elements

Device Identifier

Manufacturer Name

Manufacturer “Address”

<Contact Information>

Nomenclature system

Nomenclature term / code

<Trade / Brand Name>

<Device Model Number>

Control method (e.g., S/N, lot, …)

Device ID location

<Packaging Parent/Child Relationships>

<Alternative Device Identifiers>

<Size, Volume, Length, Gauge, Diameter>

[Additional Product Description]

Storage & Handling Conditions

Labeled as Single Use (SUD)

Sterility

<Restricted Number of Reuses>

Labeled as Containing Latex

<Authorized Representatives>

<License/Marketing Authorization or Registration Number>

[URL for Additional Information]

<Critical Warnings / Contraindication>

(From GHTF Draft Proposal for a draft guidance on Unique Device Identification (UDI) System for Medical Devices, 2010.11.04)

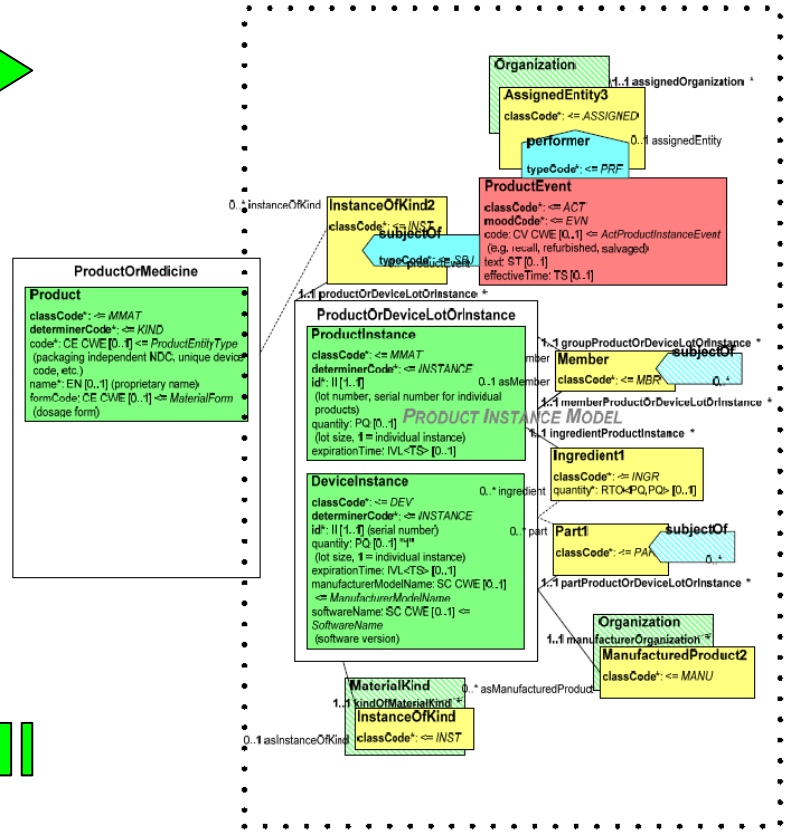
HL7 SPL Mapping

Don't Panic!

GHTF UDI Data Elements (abstract)

HL7 Implementation Guide Provides Mappings & Format Specifications

HL7 SPL / UDI XML-Based Labels



You do not have to be an HL7 v3 Expert Modeler!

GHTF UDI to HL7 SPL

HL7 SPL (rel 5) Implementation Guide + General WG Information @

wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5)

Note: Extended to support UDI.

wiki.hl7.org/images/d/d2/SPLr5_IGv1.0_-_new.pdf

Structured Product Labeling Release 5
Implementation Guide
for FDA Establishment Registration, Listing, and UDI Submission
Version 1 Revision 201008271159

SPL FDA/UDI XFORM Editor

3.1 Product data elements

Information: The listing data elements for products are provided.

128 site and product codes are for licensed minimally manipulated cell products. GS1 GTIN and HIBCC codes are used for device item codes. FDA Substance Registration System (SRS) is used for the ingredient and active moiety Unique Ingredient Identifier (UNII). The FDA submission tracking system is used for application numbers. The Code of Federal Regulations is used for monograph citations. The National Cancer Institute Thesaurus (NCIt) is used for dosage form, product characteristics, DEA schedule, unit of presentation, route of administration and equivalent codes. The Unified Codes for Units of Measure (UCUM) is used for the unit of measure. HL7 confidentiality code "B" is for business confidential information. The Global Medical Device Nomenclature (GMDN) is for device nomenclature codes.

The following is for a device:

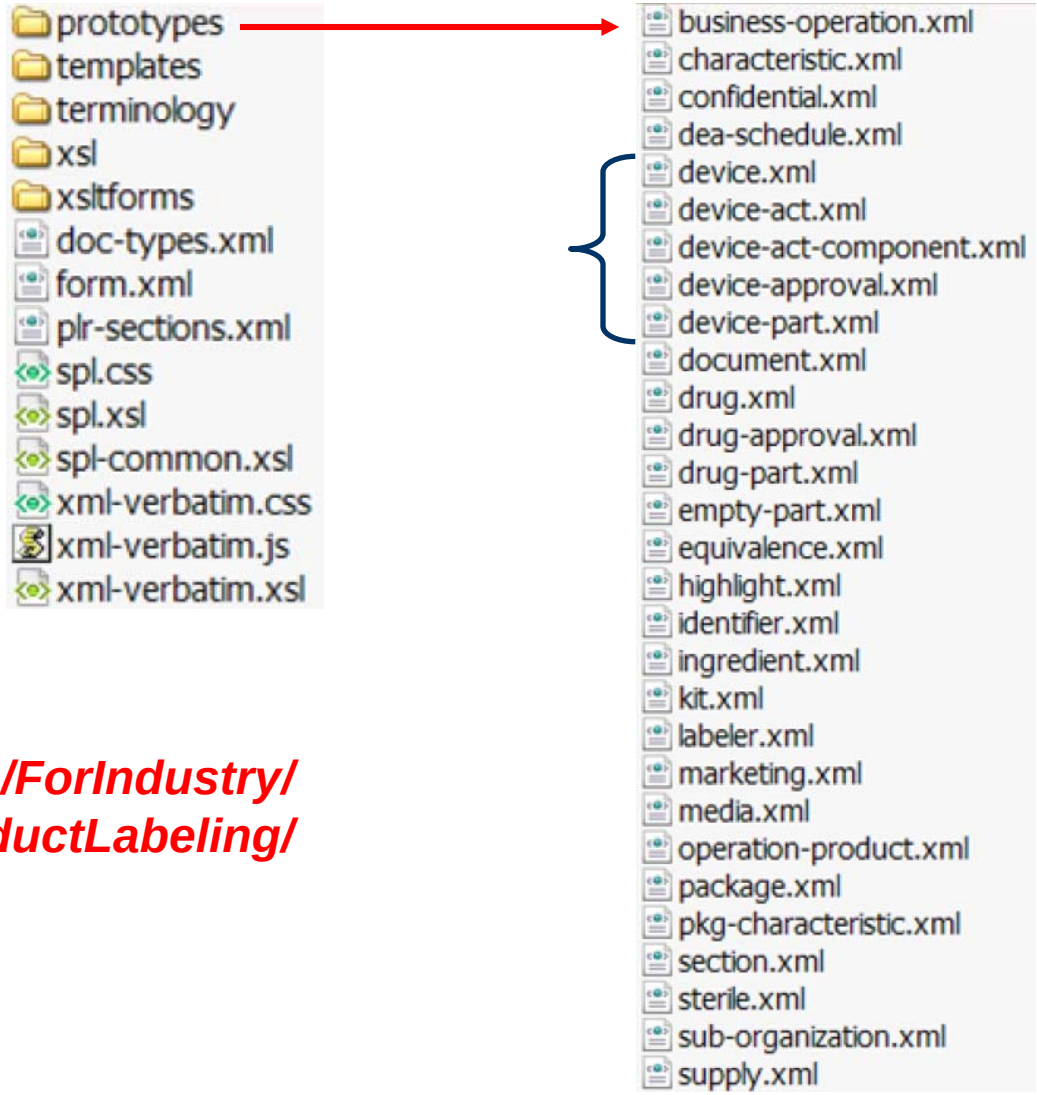
```
<subject>
  <manufacturedProduct>
    <manufacturedProduct>
      <code code="Device Item Code" codeSystem="Item Code System"/>
      <name>proprietary name <suffix>suffix to name</suffix></name>
      <desc>Brief description of product (< 512 characters)</desc>

      <asSpecializedKind>
        <generalizedMaterialKind>
          <code code="GMDN code" codeSystem="2.16.840.1.113883.6.276"
                displayName="GMDN display name"/>
        </generalizedMaterialKind>
      </asSpecializedKind>
```

Pilot Templates, …

UDI SPL Support Files (in process) provided on-line @

http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM237103.zip



SPL Editor & Validation Tooling

PragmaticData

Home

Structured Product Label (SPL)

We have designed the Structured Product Label (SPL) specification, an HL7 standard for medicinal product knowledge in both human readable and computer-interpretable format. SPL is the first comprehensive standard of medicinal products and is implemented by the U.S. FDA and all U.S. pharmaceutical industry.

The SPL standard is one of many applications of the HL7 RIM. It is a knowledge representation standard for drug products. Prior to SPL there was no data standard for medication knowledge (outside of proprietary products) able to express even the basic realities of medicines, ingredients and packaging in a computable way. All pharmaceutical manufacturers in the U.S. submit drug information to the FDA using SPL and the NLM publishes them online. The SPL knowledge base presently contains over 3200 descriptions of currently marketed drugs. SPL, which includes data relevant for clinical decision support such as adverse effects, contraindication, interactions, and monitoring requirements, serves as preliminary evidence that it is indeed possible to integrate medical knowledge into a standard which was driven by practical health information systems. Within the SPL structure all the terminologies of the U.S. federated medication terminology system come together: the NDC product code, Unique Ingredient Identifier (UNII), SNOMED CT disease / finding concepts, the VA NDF-RT system's ChemicalStructure classes (originating in the NLM MeSH system), physiologic effect and the mechanism of action terms (described in detail below). SPL also combines several smaller vocabularies from the NCI Thesaurus and the Unified Code for Units of Measure.

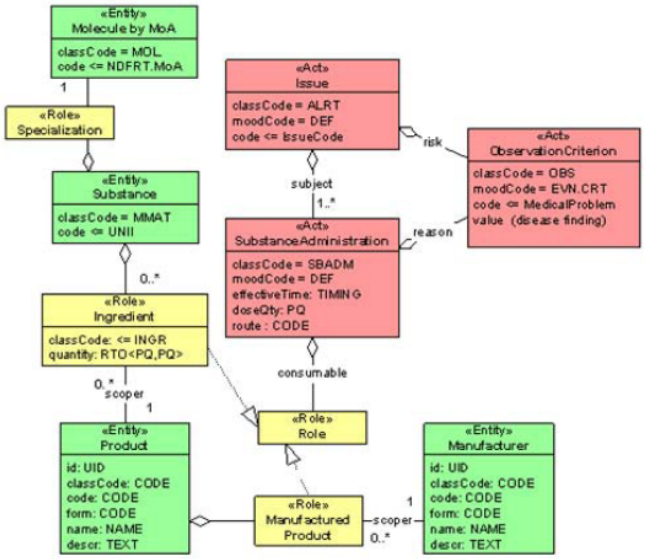


Figure 1: The SPL model is a realist ontology of medical products, therefore it can represent the contents of the NDF-RT itself (Right). This project will focus on detailing the Mechanism of Action (MoA) annotation.

Main Menu
- Home
- About Us
- Our Services
- Our Portfolio
- Contact Us
- News
- Site Map

User Menu
- Your Details
- Add About Us
- Add Portfolio Item
- Add News
- Add WebLink
- Check-In My Items
- Logout
- Trac Sites
- Add Services

Login Form

Hi, ToddCooper

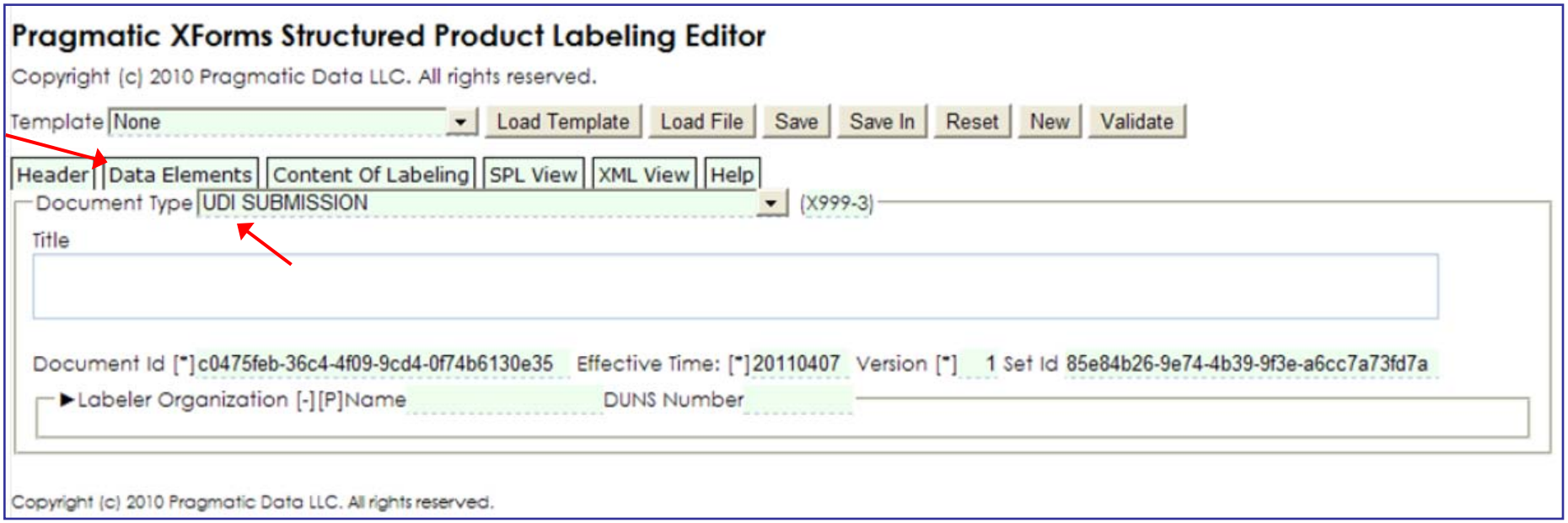
Logout

Syndicate

RSS 2.0

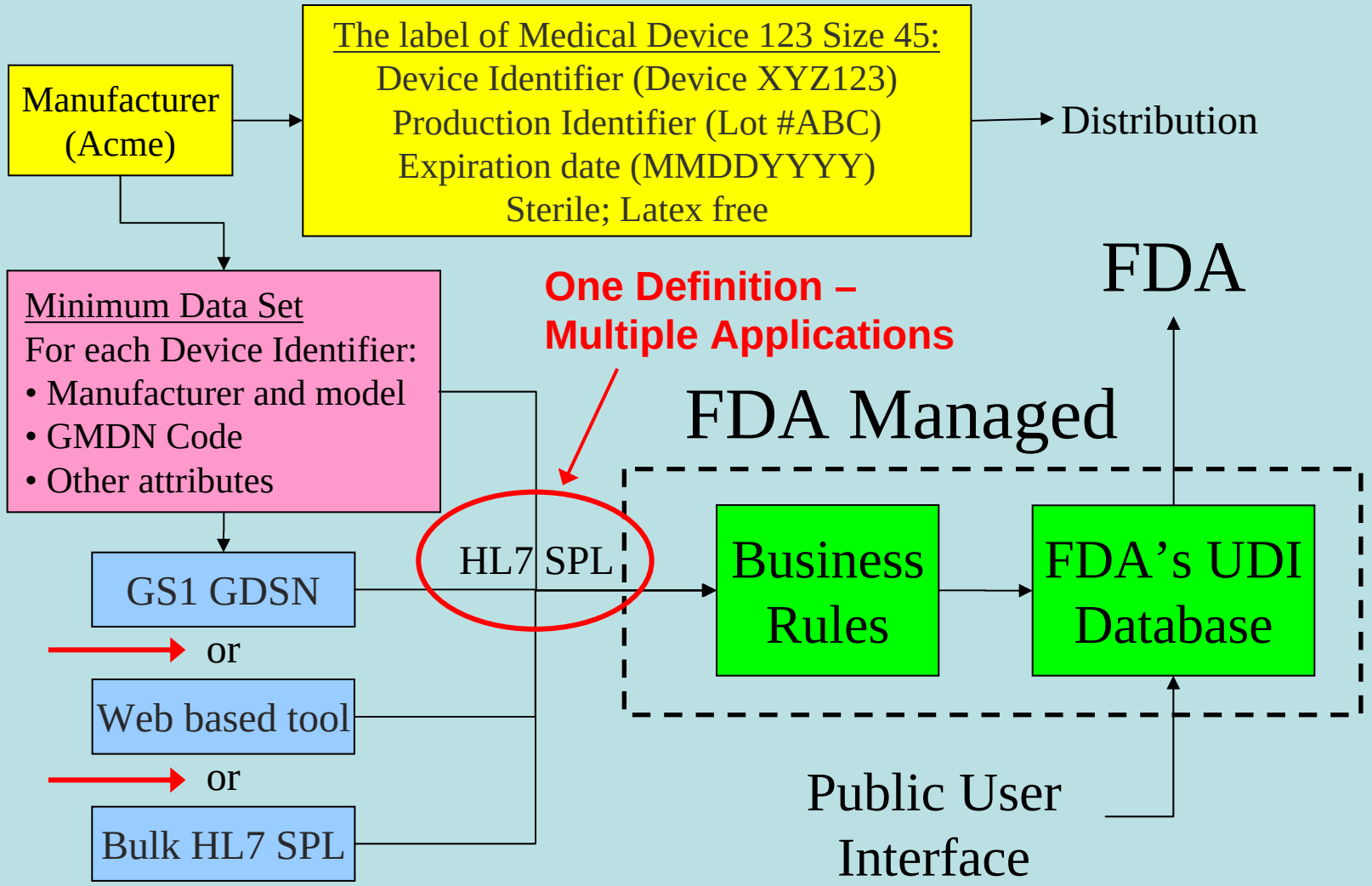
www.PragmaticData.com

SPL FDA/UDI XFORM Editor



@ www.PragmaticData.com/spl/form/

UDI – The Big Picture

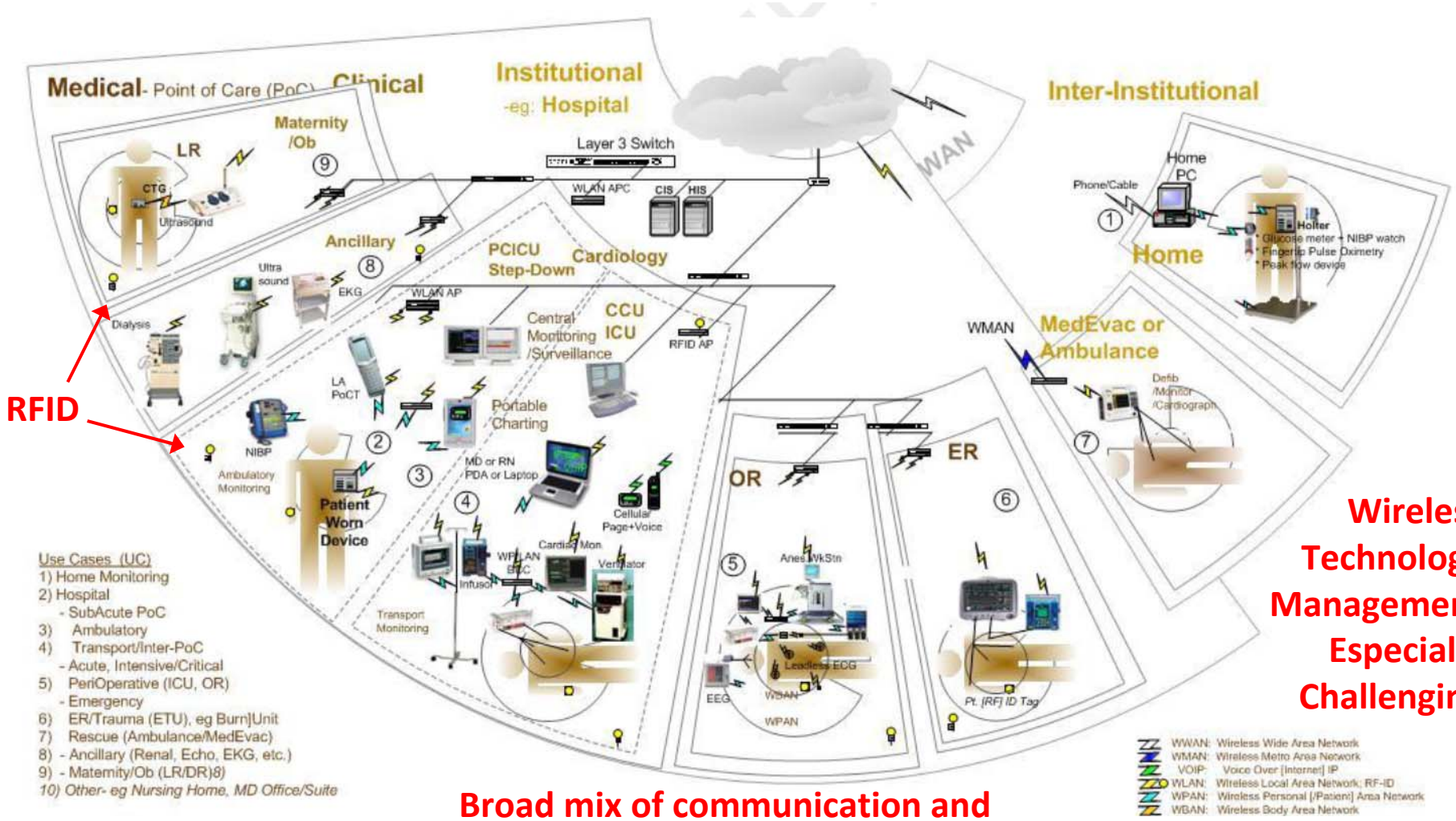


(From Jay Crowley, FDA CDRH, 2011.04.06)

The Bigger Picture

(*Welcome to my world…!*)

Support All Care Contexts

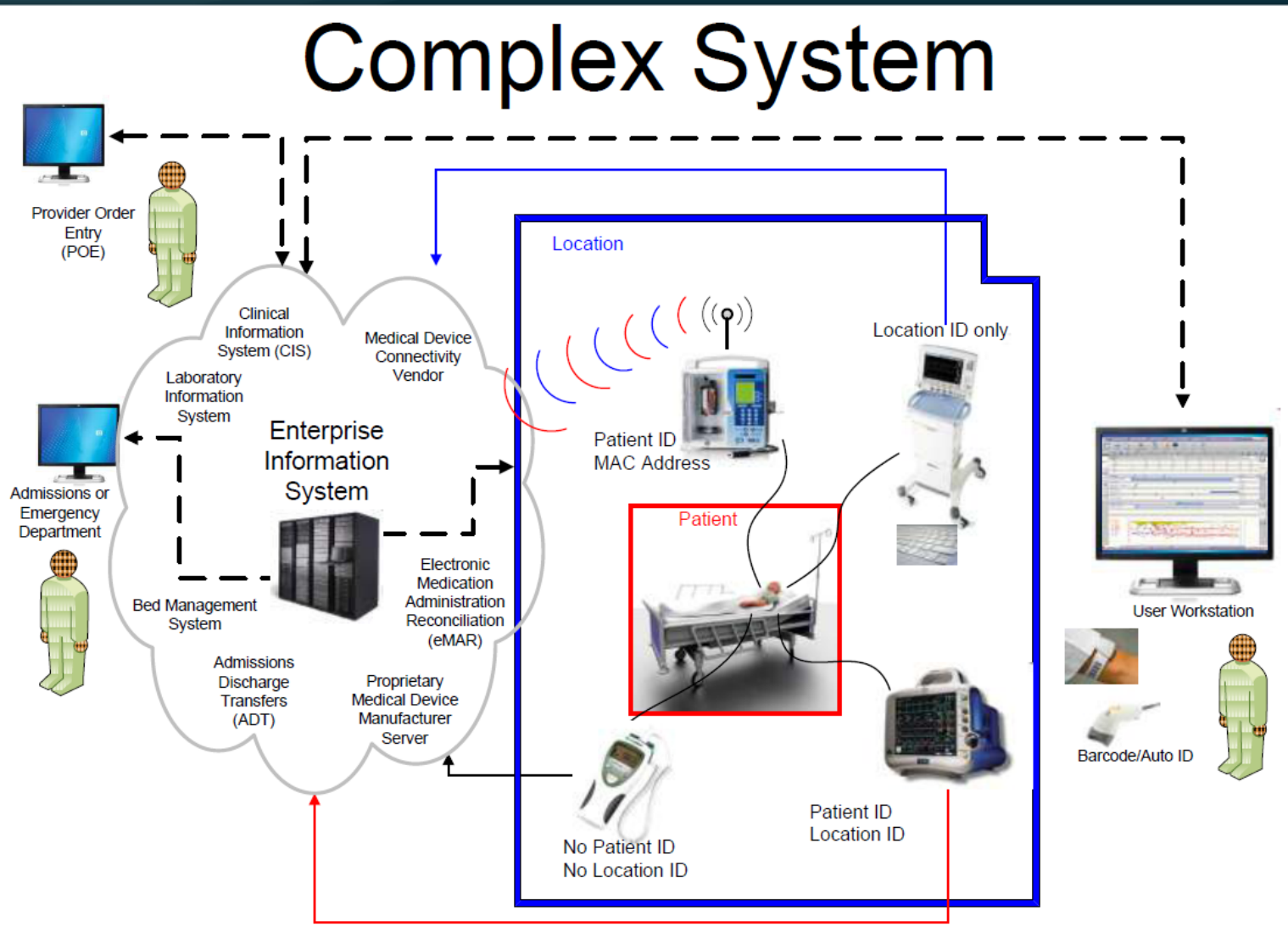


Wireless Technology Management Especially Challenging

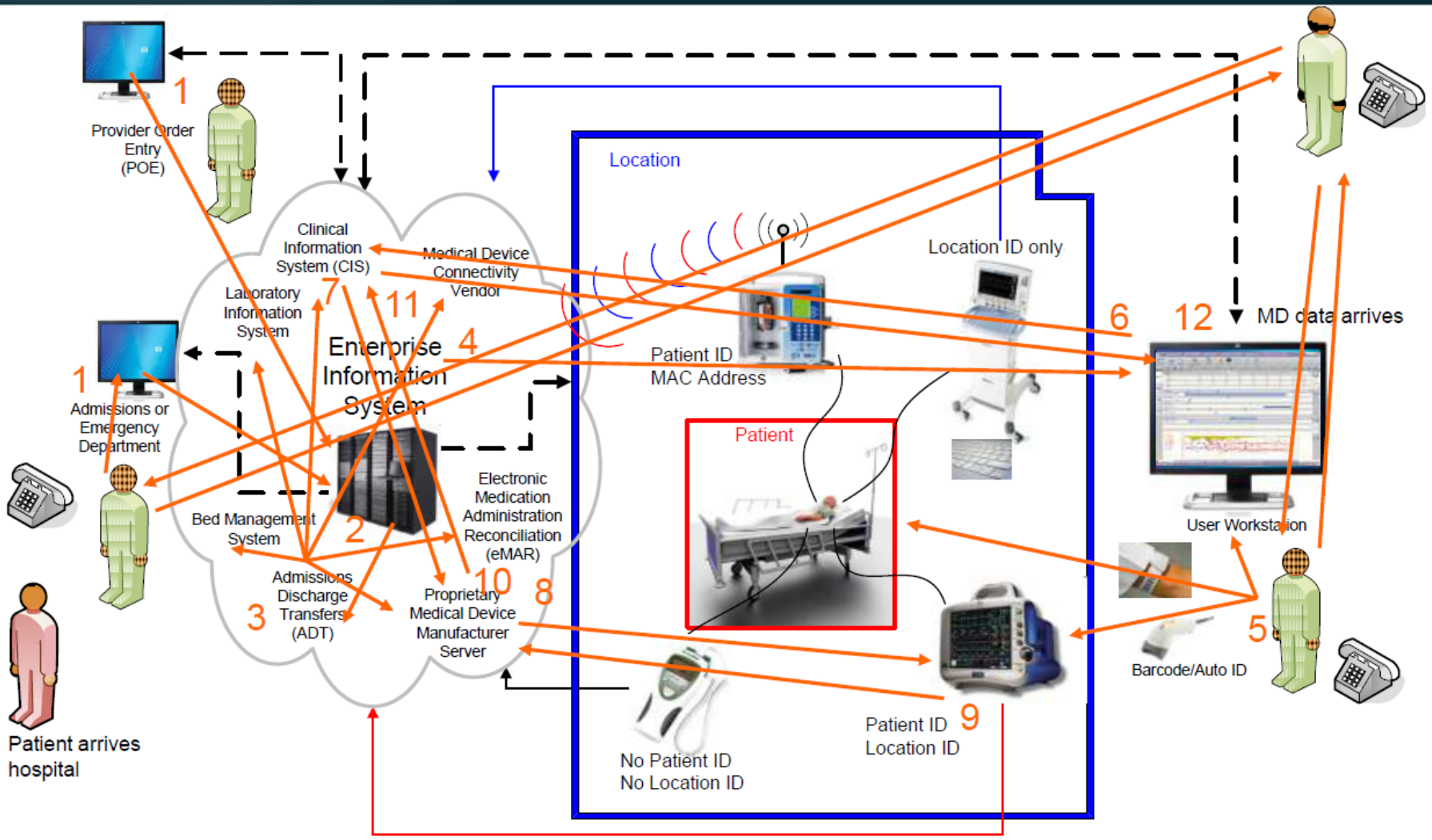
Broad mix of communication and medical technologies – must coexist!

(Jan Wittenber, Philips Medical, HITSP/TN905)

Where's the ID?



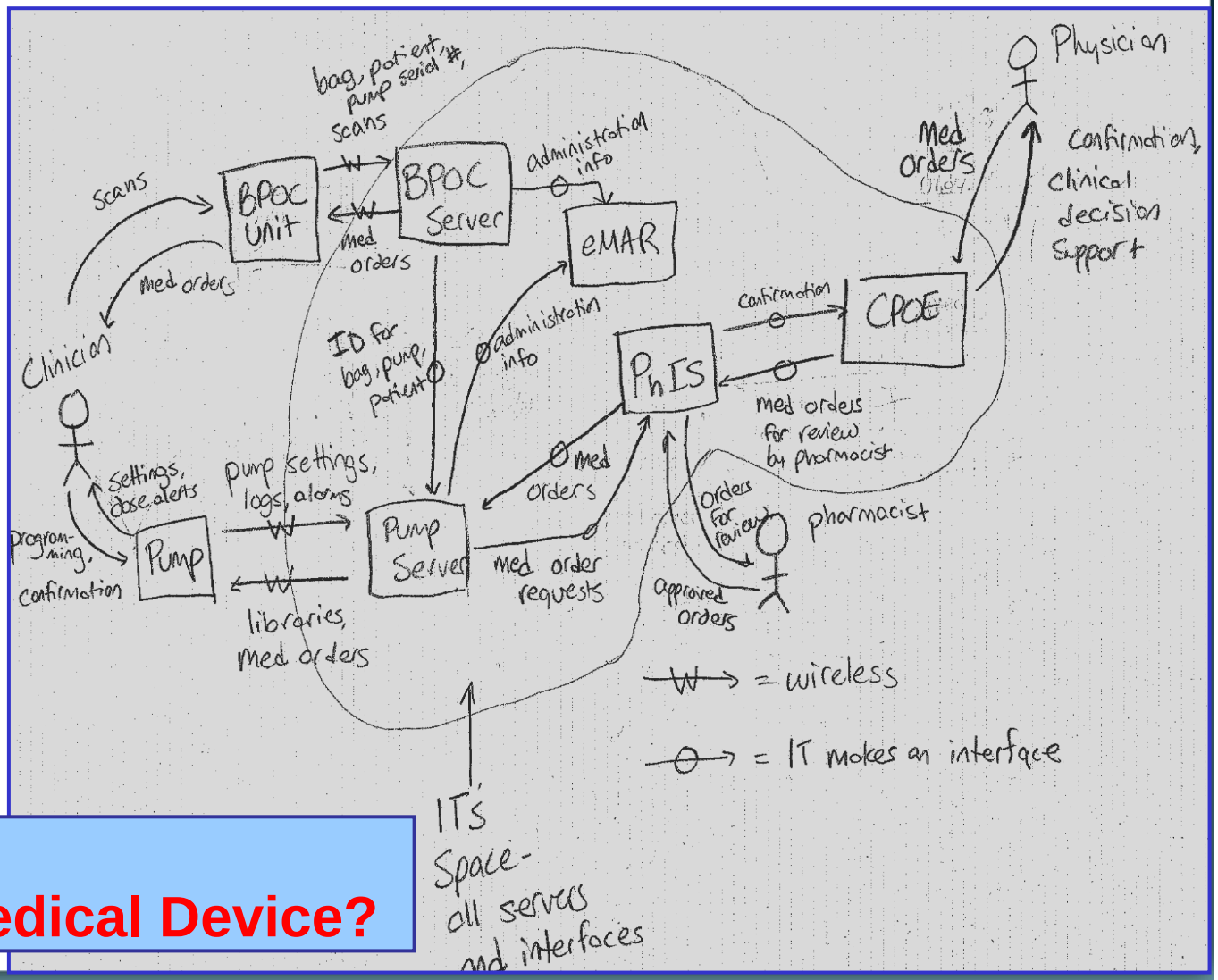
#1 Problem: Patient/Device ID!



Med Admin/Systems of Systems

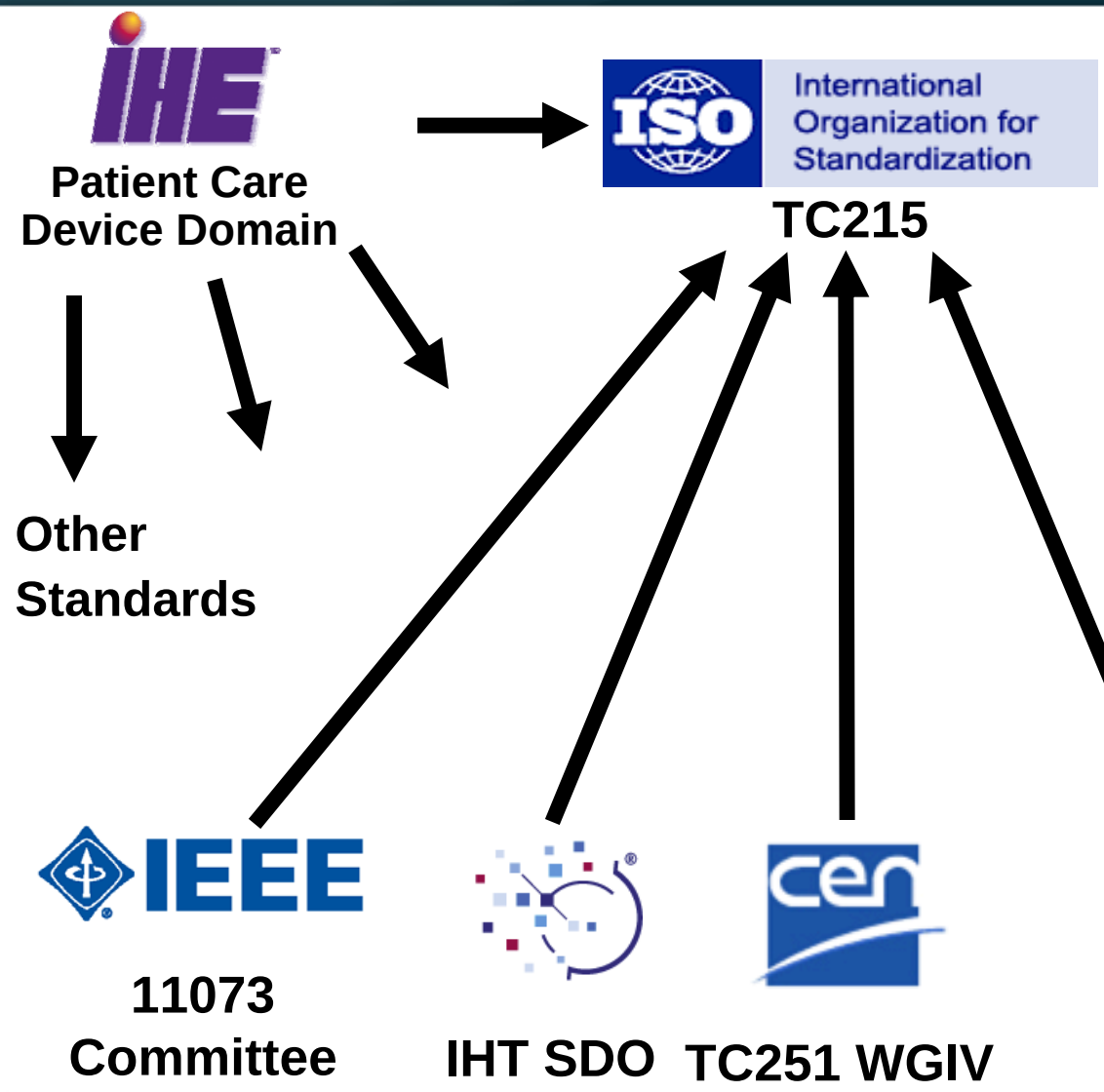
It's not just interfacing the infusion pumps!

Many clinical systems must be integrated – from many vendors – using many technologies!



FDA MDDS?
Software as a Medical Device?

SDO Coordination



Single set of Internationally Harmonized Medical Device Informatics & Interoperability Standards

Other groups:

- *Continua Health Alliance*
- *ISO/IEC JWG7 – IEC 80001-1*

What's being done?

How are these problems being addressed?

- ✓ *Standards are ready … implementation?*
  Products are starting to hit the market!
- ✓ *HL7 version 2 messaging (not Ver. 3!) is the primary transport for communicating medical device data to EHRs – Modeling helps ensure consistency*
- ✓ *ISO/IEEE 11073 is the primary semantic content standard (both acute & personal health devices)*
- ✓ *NIST continues to develop open validation tooling*
- ✓ *IHE Develops interoperability profiles that leverage the above standards & tooling …*

But system identifiers remain a total mess!

Networked Device IDs

From the IHE PCD Technical Framework:

What's missing?!

Identifying with an EUI-64. Namespace ID (EI-2) is optional in this case and may contain a locally unique name for the application implementing PCD actor(s). Universal ID (HD-2) contains the EUI-64 identifier as a hexadecimal string. The IEEE defined 64-bit extended unique identifier (EUI-64) is a concatenation of the 24-bit company_id value assigned by the IEEE Registration Authority, and a 40-bit extension identifier assigned by the organization having that company_id assignment. Third component (required): EUI-64.

Identifying with an OID. "Namespace ID" (EI-2) contains the name of the assigning authority, "Universal ID" (HD-2) containing its universal OID, and "Universal ID Type" (EI-4) containing the value ISO.

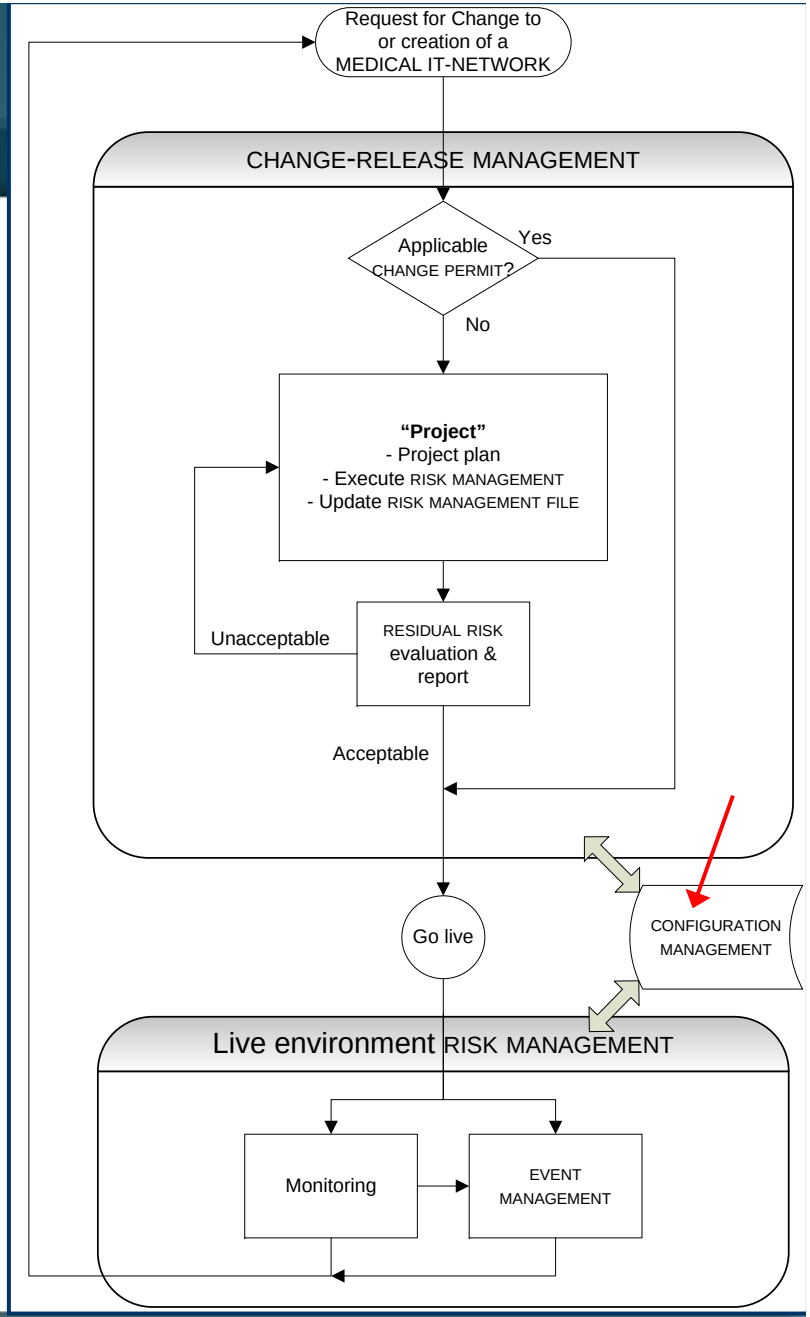
Identifying with a URI. The Universal Resource Identifier, defined in IETF RFC 3306, encompasses the familiar Uniform Resource Locator (the URL "internet address" of a website, for example), and the Universal Resource Name, which need not identify a web resource but uniquely identifies an entity according to a number of unique identifier schemes, including some of the others listed, such as OIDs (which can be made into URIs simply by prefixing the OID string with "urn:oid:".

Identifying with a DSN. When the assigning authority is an information system or a manufacturer, it is acceptable to use a Domain Name Service name that uniquely identifies it. An IP address is a form of DSN, so it is also acceptable. These are less stable and permanent than the other Unique ID systems, which is why they are the least preferred.

IEC 80001-1 Risk Management for IT-Networks Incorporating Medical Devices…

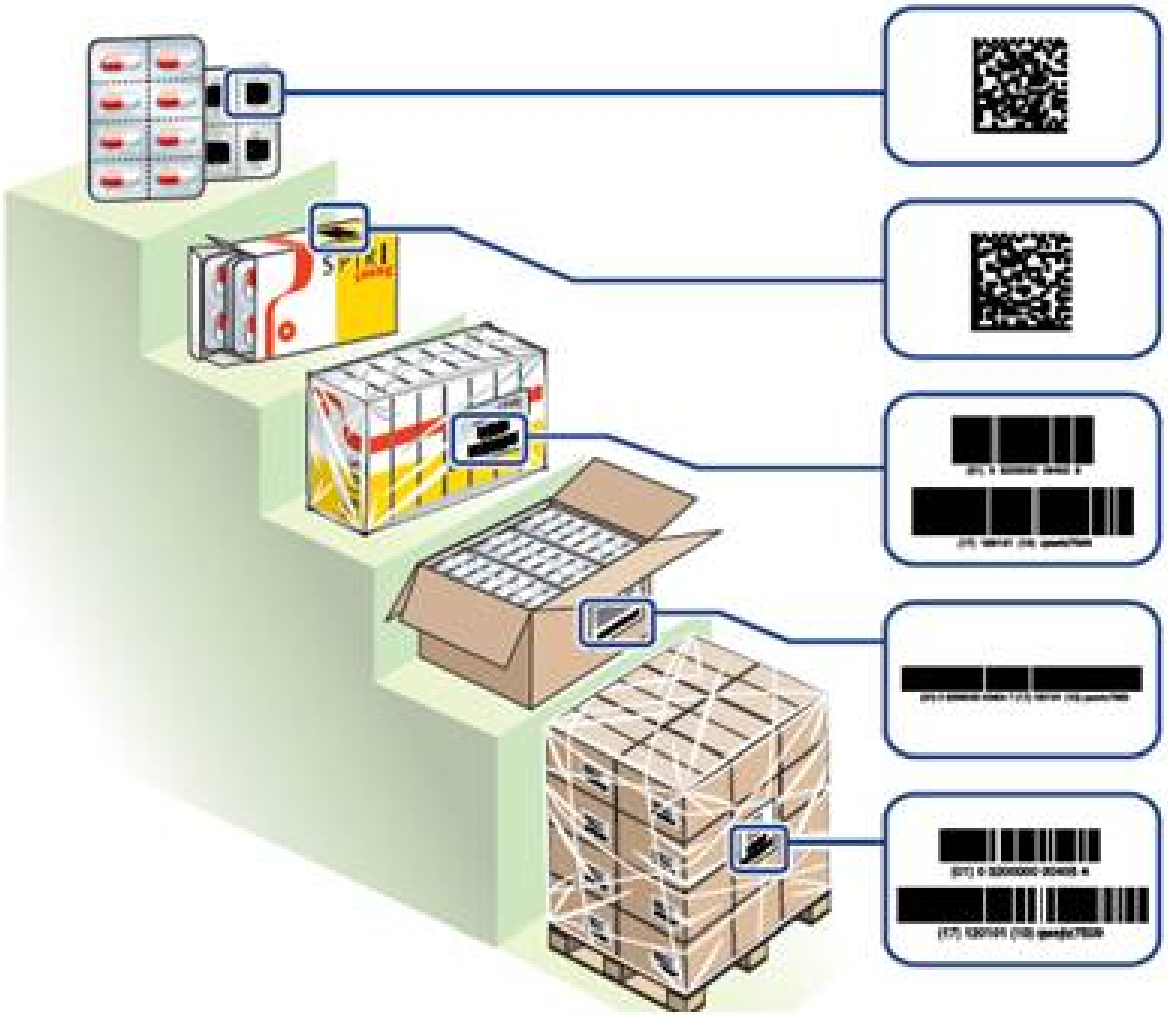
- ✓ Full Device & Network Life Cycle Process
- ✓ 3 Key Characteristics:
  - Safety
  - Effectiveness
  - Data & System Security

Built on knowing what is where when & its operational status / effectiveness



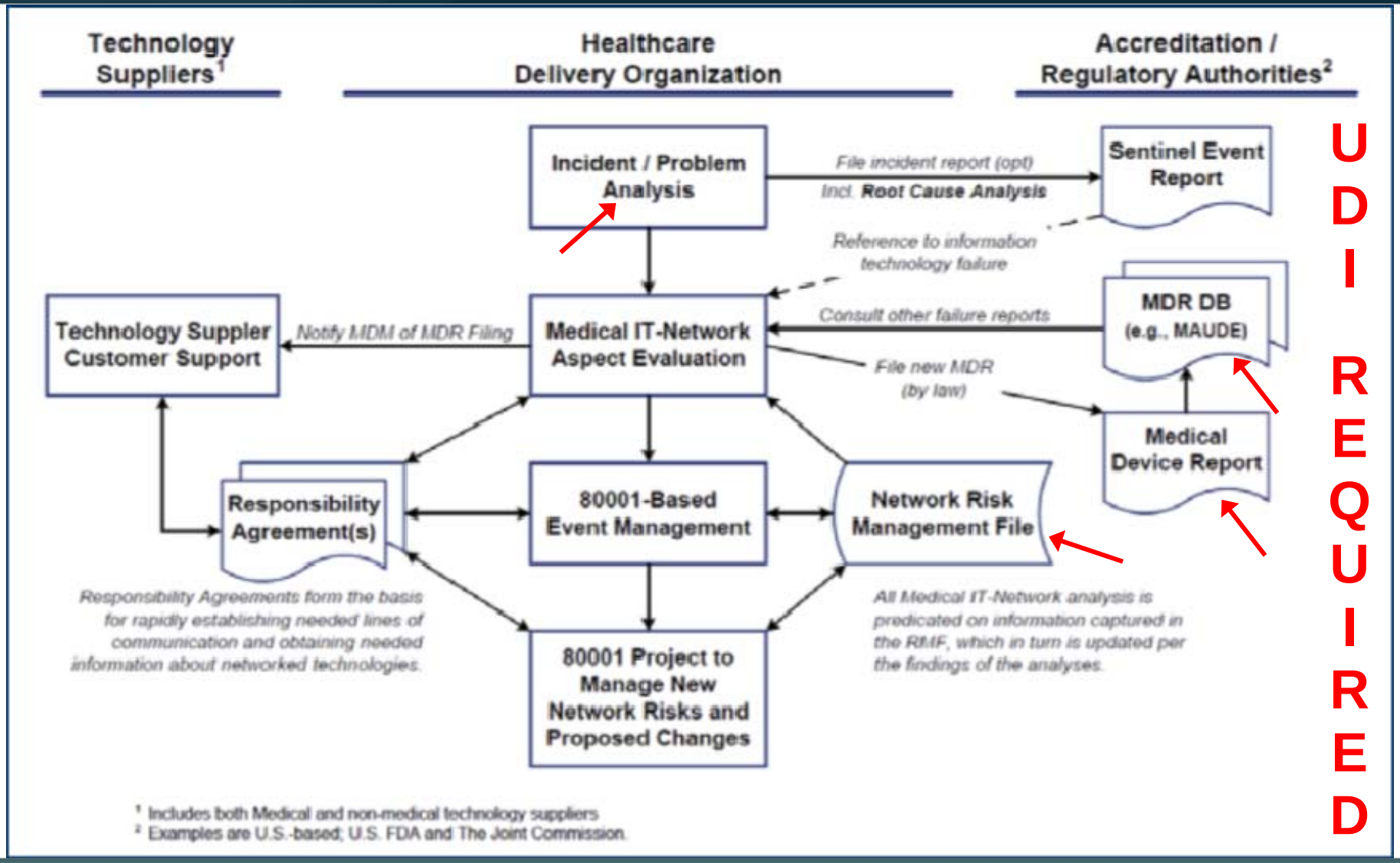
(IEC 80001-1:2010, Figure 2)

RM "Chain" Continuity



Analogous to Supply Chain Management, UDI facilitates continuity of monitoring and maintenance of manufacturer's and end user's risk control measures for networked medical technology

80001-based Issue Management



(AAMI Getting Started with IEC 80001, Figure 13)

Conclusions

1. *Aim at one UDI Model-to-SPL/CPM mapping to support many applications (supply chain + reg + clinical integration)*
2. *Medical Device Identification:*

Much has been done …

Standards in place & evolving …

Reality? it's still a mess!

Get Involved!!!

GS1, HL7, ISO, IEEE, IHE …

Thank You!

www.80001*Experts*.com

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