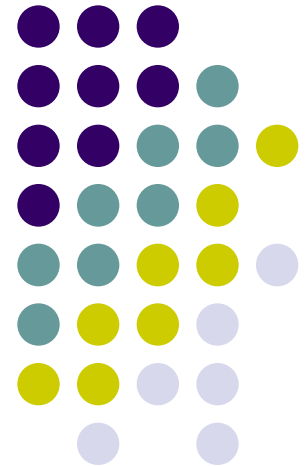
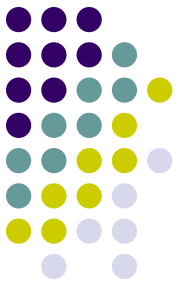


# UDI/Standards Adoption for Medical Device Manufacturers

Medical Device Supply Chain Council

December 2, 2009



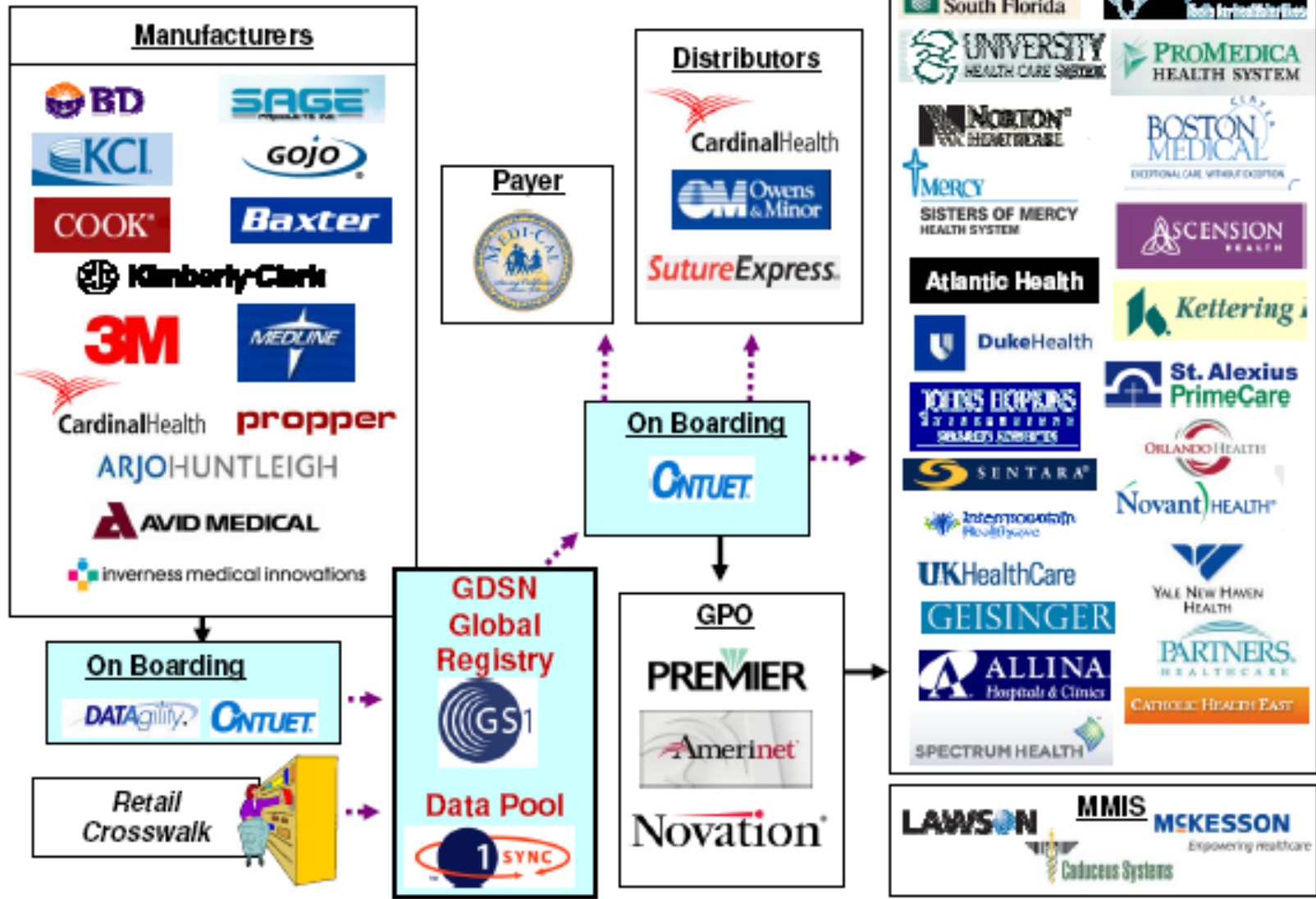


## The UDI is coming.....

- Federal Legislation
- Multiple public meetings hosted by FDA
- Request for Comments
- Recently Completed Pilot
  - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/ucm191770.htm>
- Active participation by FDA in various Industry & Standards meetings
- GHTF – This is not just a **US** issue



# DoD Healthcare GDSN Pilot

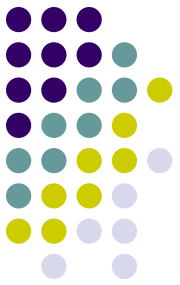




## Assuming UDI is coming.....

There are two basic choices

- Wait for the regulations and implementation timeline to be completely defined before beginning preparation
- or
- Begin the process of preparing your organization for the inevitable



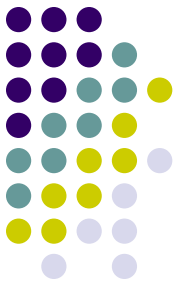
## Assuming UDI is coming.....

There are two basic choices:

- Wait for the regulations and implementation timeline to be completely defined before beginning preparation
- or
- Begin the process of preparing your organization for the inevitable

The purpose of today's meeting is to provide an opportunity to discuss the second option and expand our mutual understanding of the challenges and opportunities

# UDI & GS1

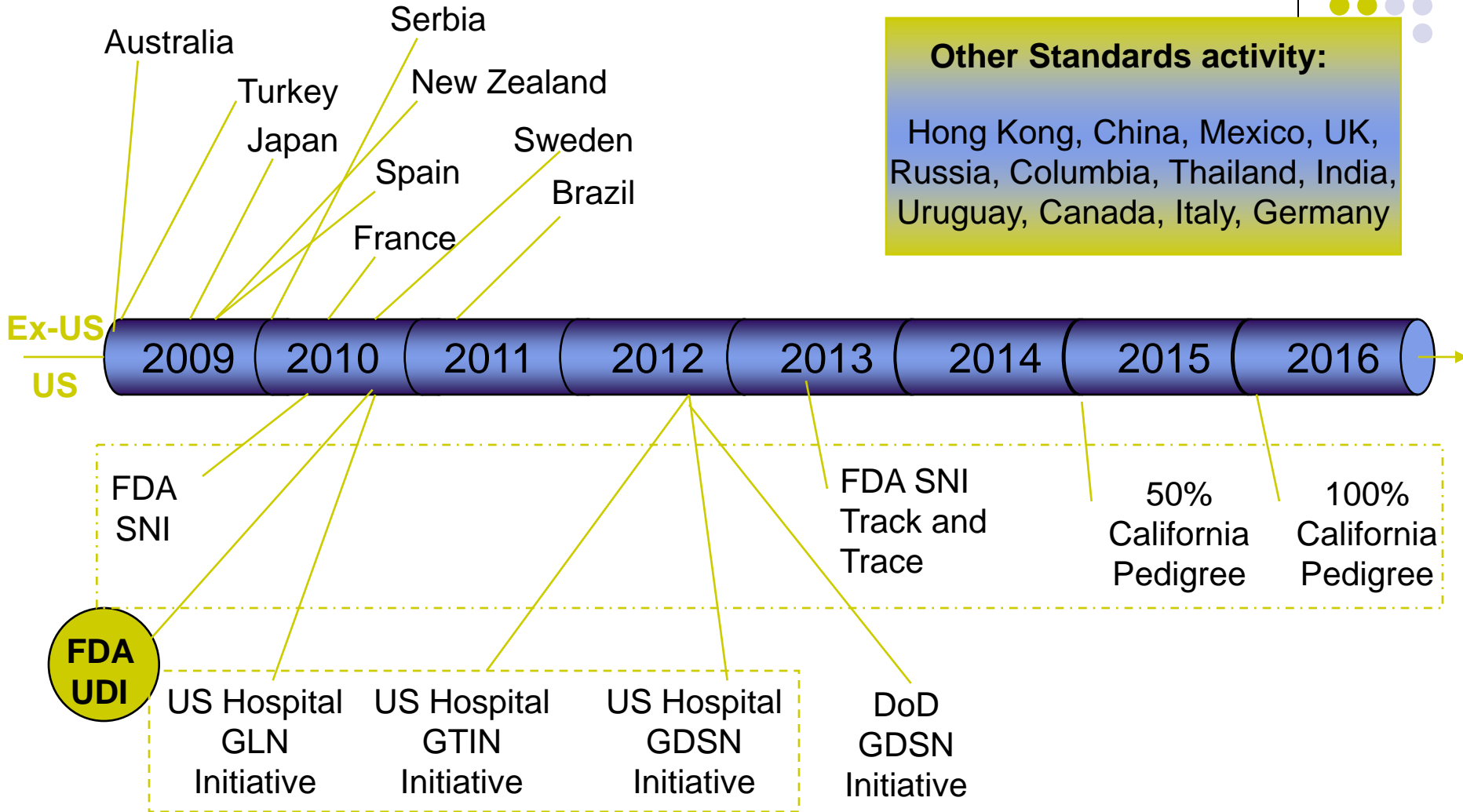
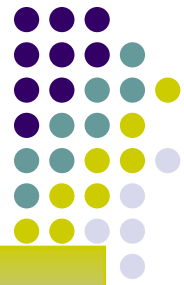


	GS1 Standards				
	GTIN	GLN	GDSN	HIBCC	Other
UDI	X	X	X	X	X
US Hospital Initiatives	X	X	X		

It is projected that GS1 standards will meet the UDI expected requirements.



# Various Initiatives Utilizing Standards



**Other Standards activity:**  
 Hong Kong, China, Mexico, UK, Russia, Columbia, Thailand, India, Uruguay, Canada, Italy, Germany

# UDI can be a challenge, depending on the type of product



**Glucose  
Tester**



**Laboratory Analyzer**

**HUMIRA™**  
(adalimumab)



**Rx Syringe Pen**

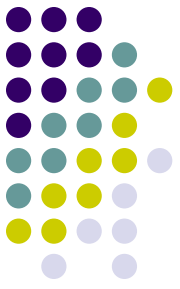


**Wound Suture**



**Vascular Stent**



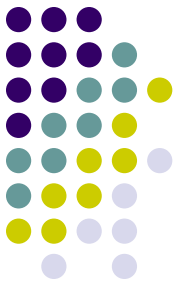


## A Common Situation

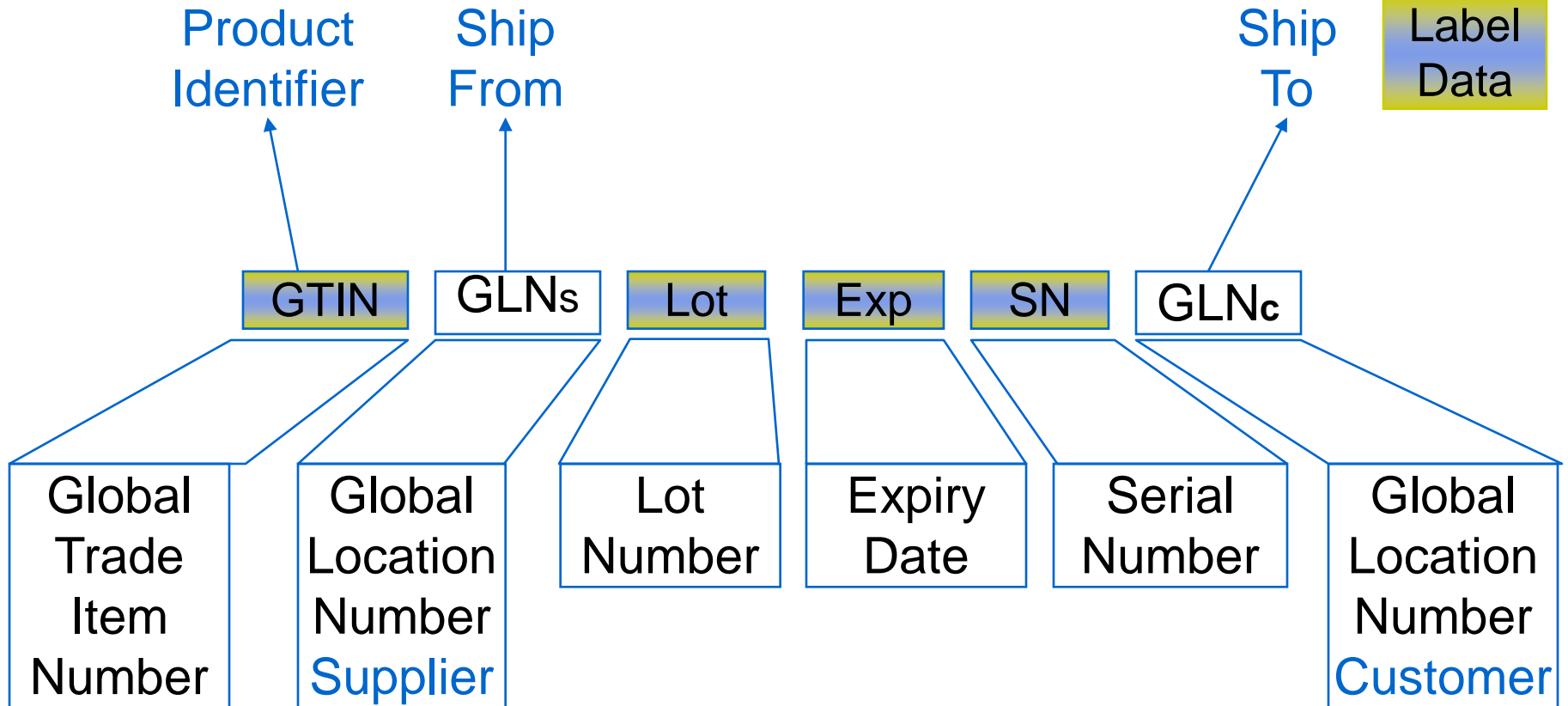
There are two major issues:

- You do not have the right data, in the right format
  - Standardized, common data elements
- Your data cannot be shared
  - Electronic – In your Systems and Accessible
  - Physical – On the Package

# GS1 Standard, Common Data Elements



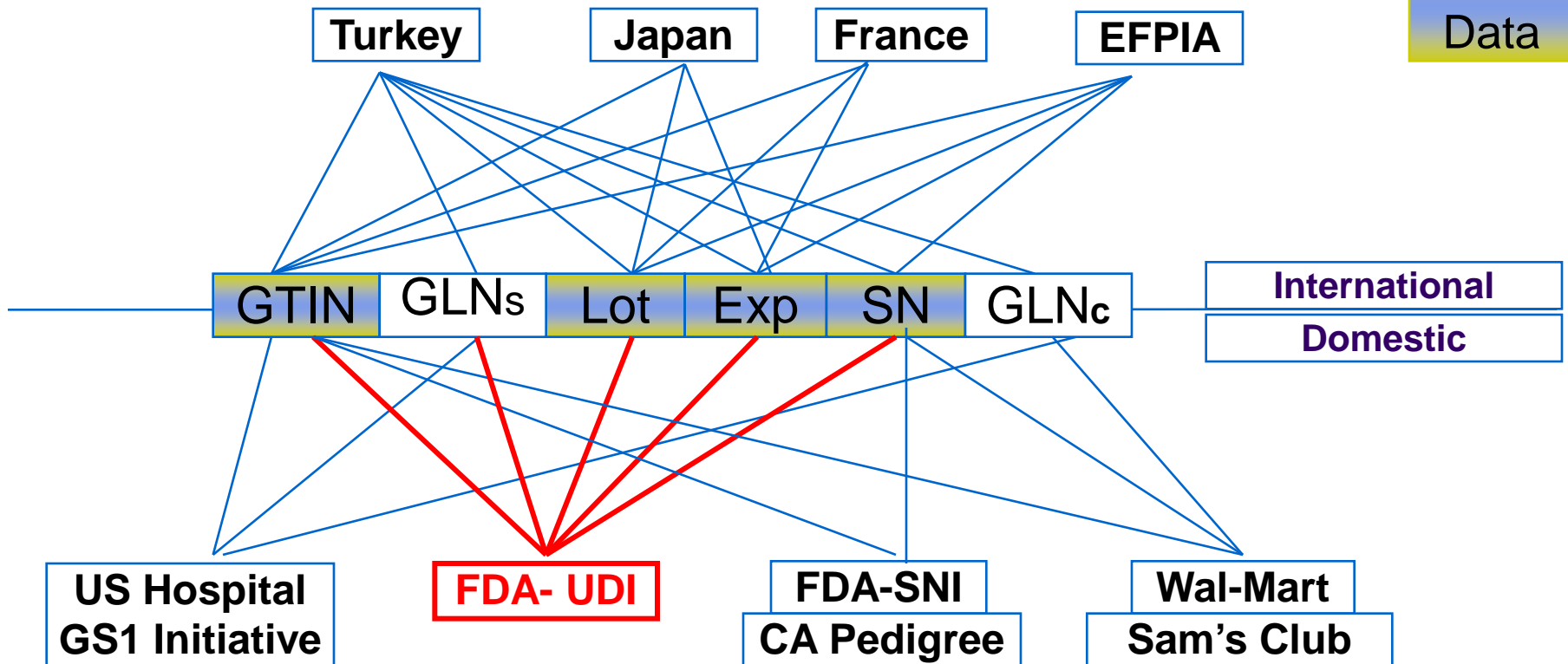
Label  
Data



# All of the initiatives use some combination of these (6) data elements



Label  
Data



# Label requirements vary by initiative



Turkey Japan France EFPIA

GTIN GLNs Lot Exp SN GLNc

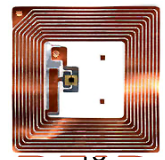
International  
Domestic

**FDA-UDI**

US Hospital  
GS1 Initiative

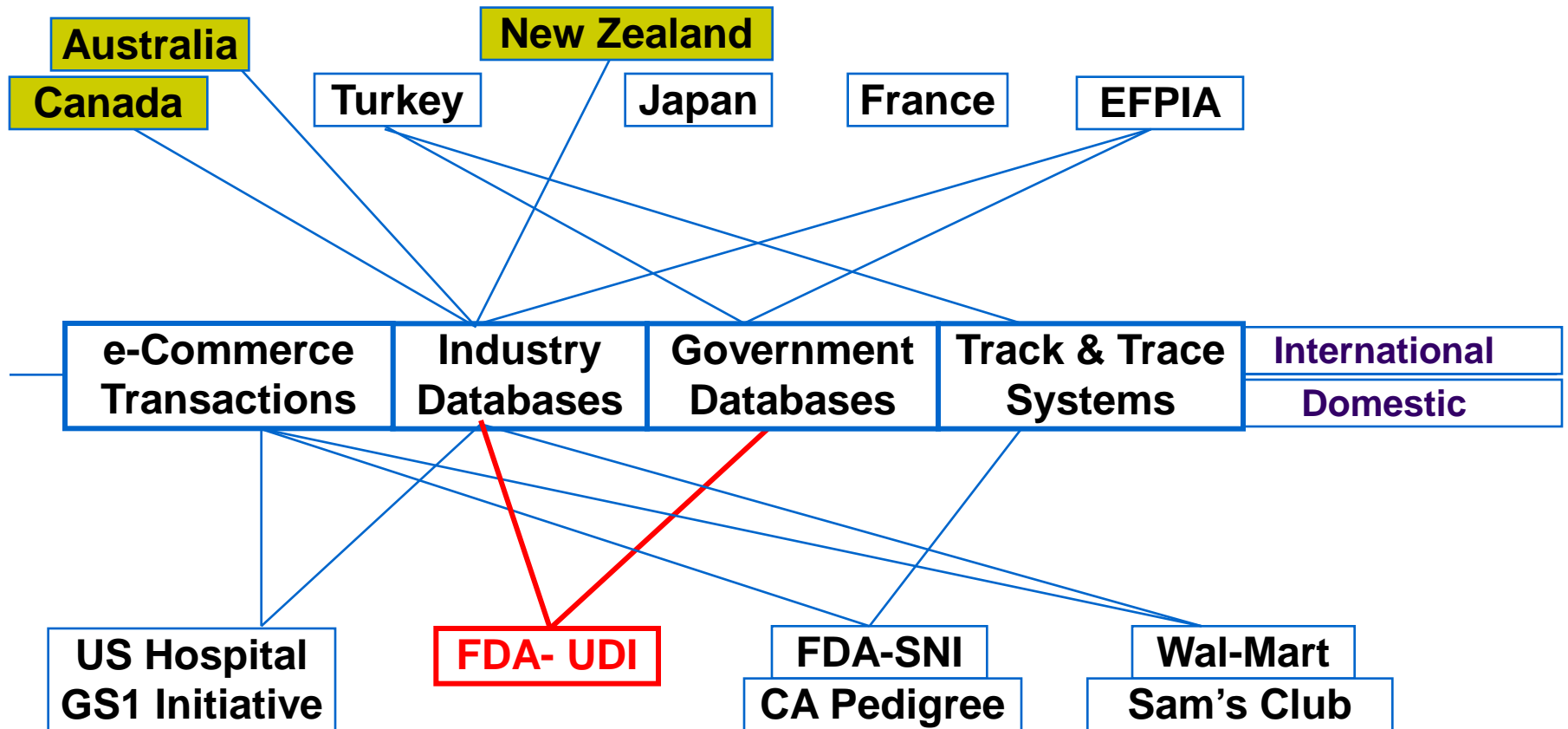
FDA-SNI  
CA Pedigree

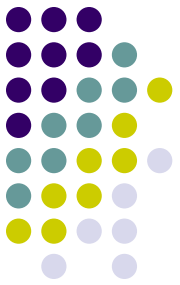
Wal-Mart  
Sam's Club





# Data sharing requirements vary by initiative

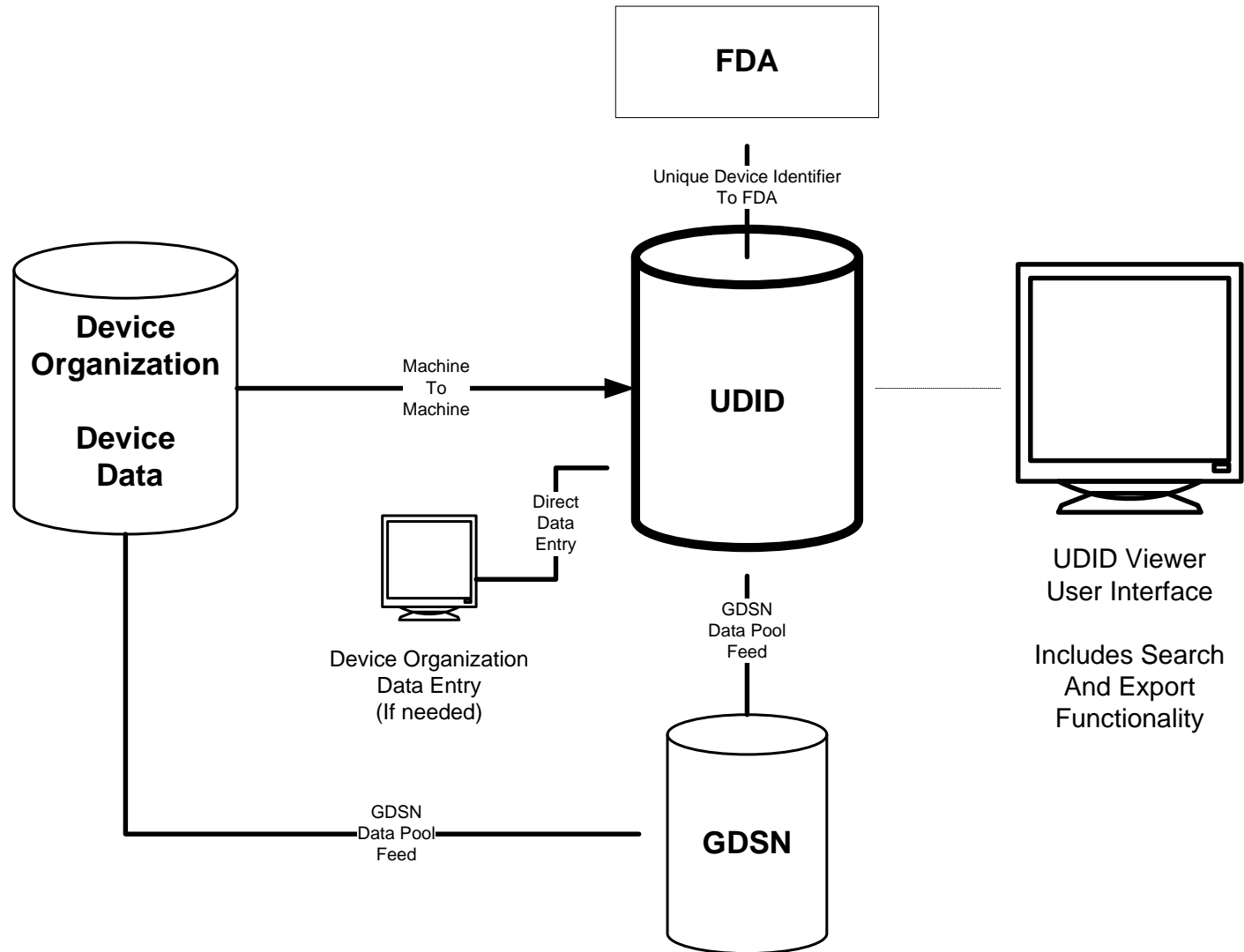
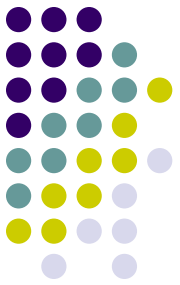


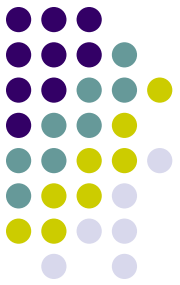


# Suggested UDI Database Information

- UDI Type/Code\*
- Product Number\*
- FDA Product Code\*
- Status\*
- Country of Origin, Manufacture & Intended Sale
- US Marketing Authorization Type/Code\*
- US Marketing Authorization Type/Code\*
- Brand Name
- GMDN & Preferred Terms
- Unique Device Identifier Description- Abbreviated\* & Full
- Labeled as containing Known Allergens
- Storage Handling Temperature
- Storage Handling Humidity
- Unit of Measure\*
- Storage Handling Temperature
- US Marketing Authorization Type & Code\*

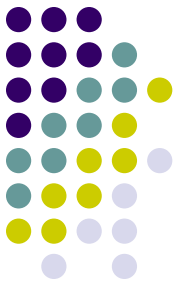
# UDI Database Proposal





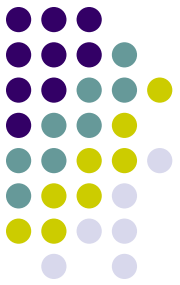
## Questions to Consider

- What is the target?
- Is it a Local or Global scope?
- Are there other initiatives to consider?
- Who are all of the stakeholders?
- Where is the data today?
- How much of your product is sourced via TPM versus self-manufacture?



## Actions to Consider

- Identify Executive Sponsor
- Identify Project Manager
- Define Project Team - Cross Functional
- Begin Self Assessment
  - Product Identification
  - Product Attributes
  - Customer Identification
  - Systems Analysis
- Consider Pilot (Internal & External)



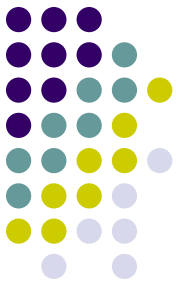
# Opportunities for ROI

## Streamlined Supply Chain Management

- Standardized Equipment
- Standardized Systems
- Improved Efficiencies
- Improved Inventory Management

## Streamlined Partner Relationships

- Improved Data Sharing
- Enhanced Data Analytics
- ETDBW – Easy To Do Business With



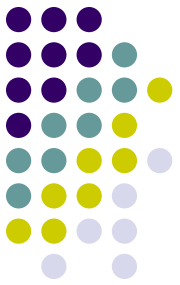
# Opportunities for ROI

## Expanded use of Auto-ID Technologies

- Reduced data transfer errors

## Improved Patient Safety

- Streamline Recall Processes
- Reduce Illegal Diversion
- Enable Item Level Serialization
- Improve Track and Trace Capabilities
- Reduce Risk of Counterfeits



## Last thoughts....

- Executive Support will be a challenge
- There is a business case. Find it!
- Education and Awareness are key
- This is not just a supply chain or regulatory or quality or engineering issue. It's ALL of them!
- Don't underestimate the degree of difficulty
- Don't wait to get started