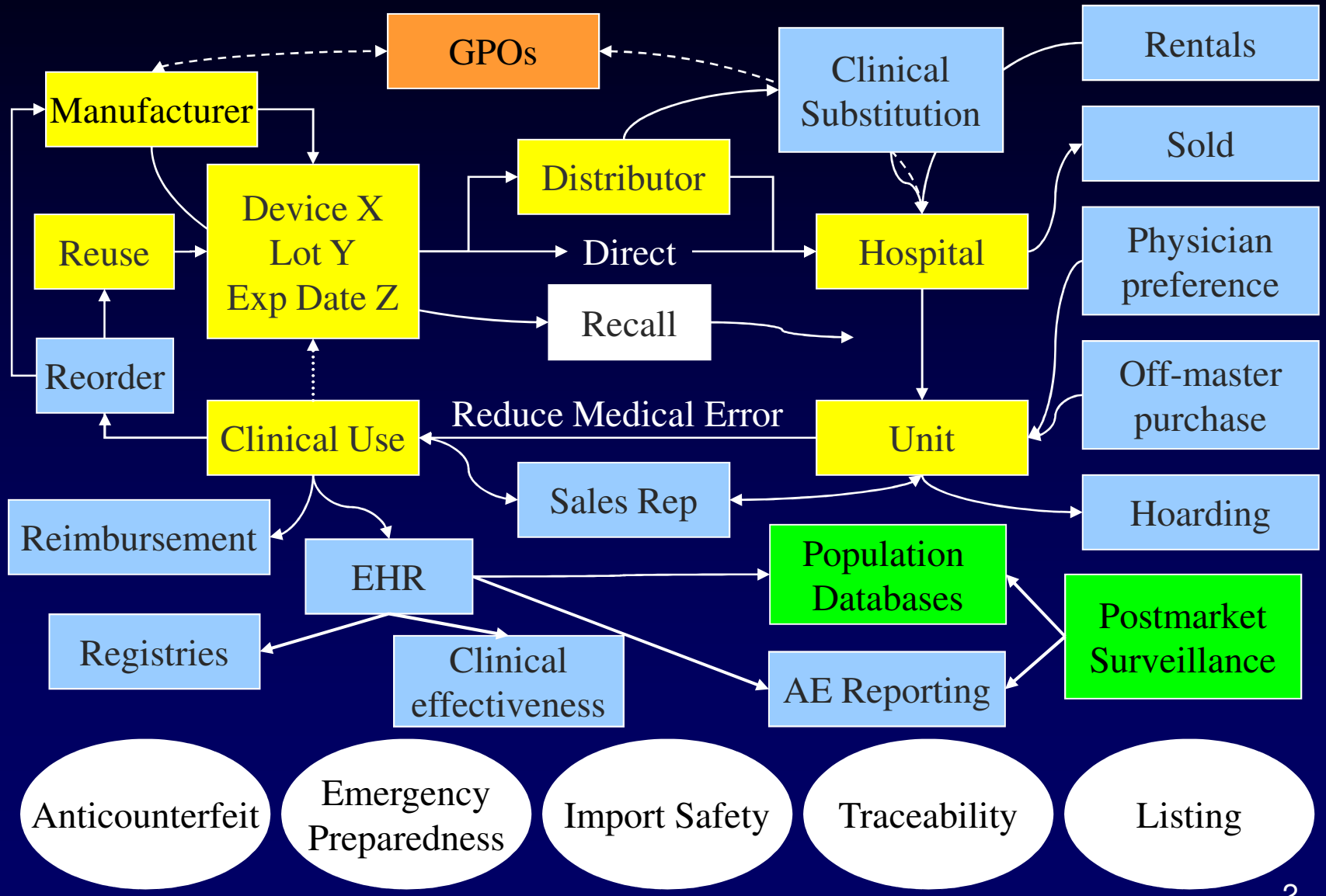
FDA's Unique Device Identification Program

Jay Crowley
Senior Advisor for Patient Safety
Food and Drug Administration
jay.crowley@fda.hhs.gov
301-980-1936

Device Information Lifecycle

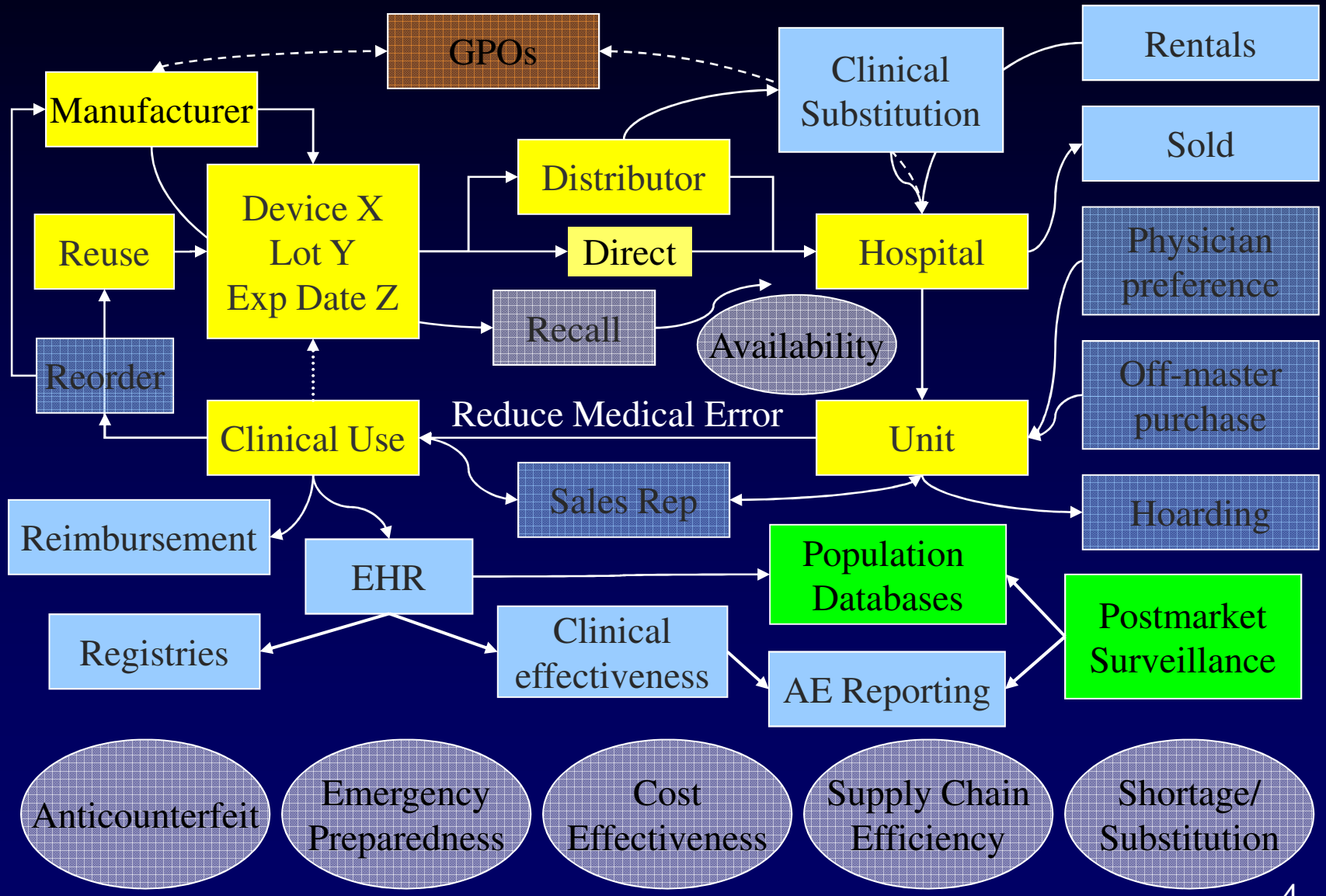


UDI Can Improve… Visibility

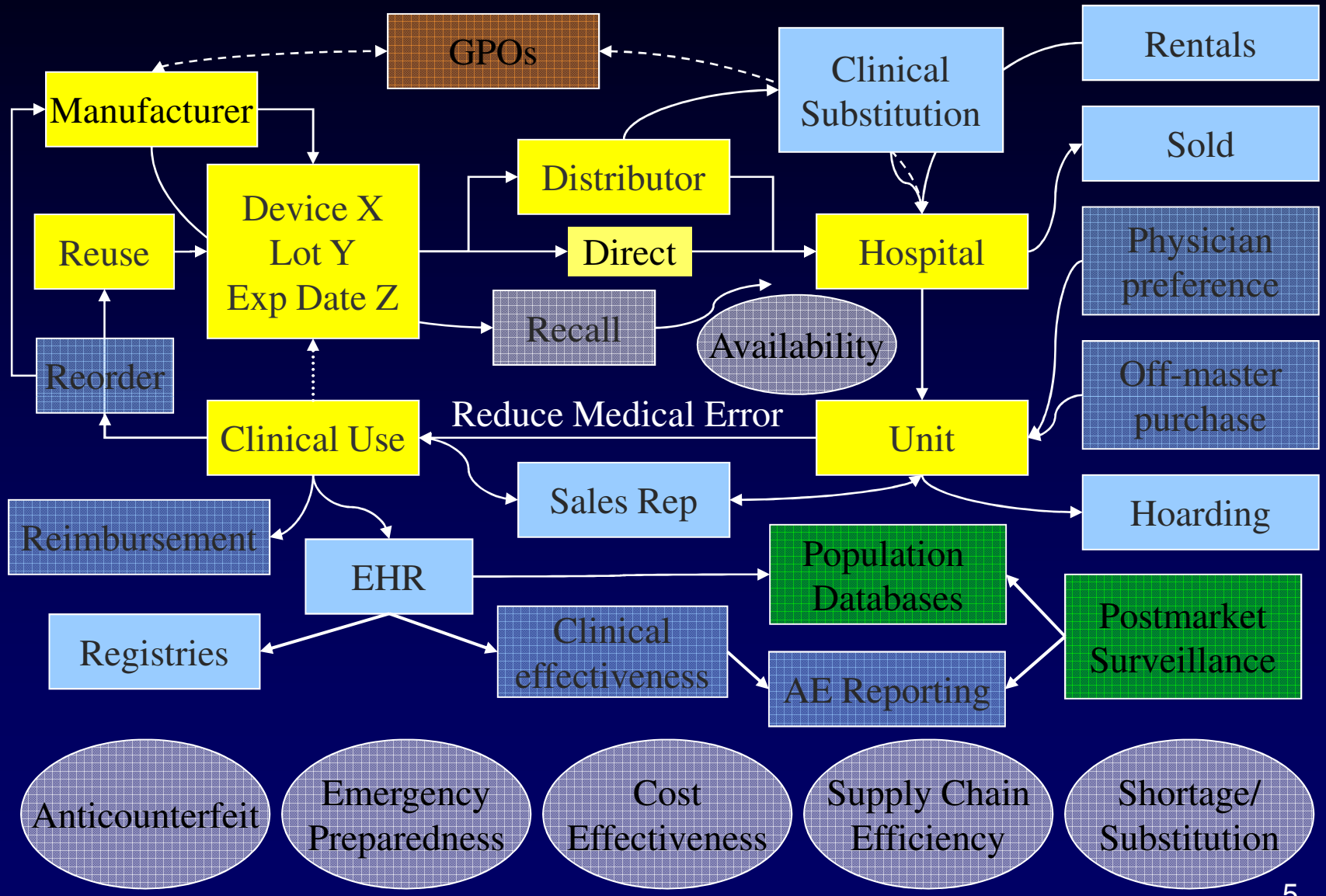
- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Clinical/cost effectiveness (registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors

- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

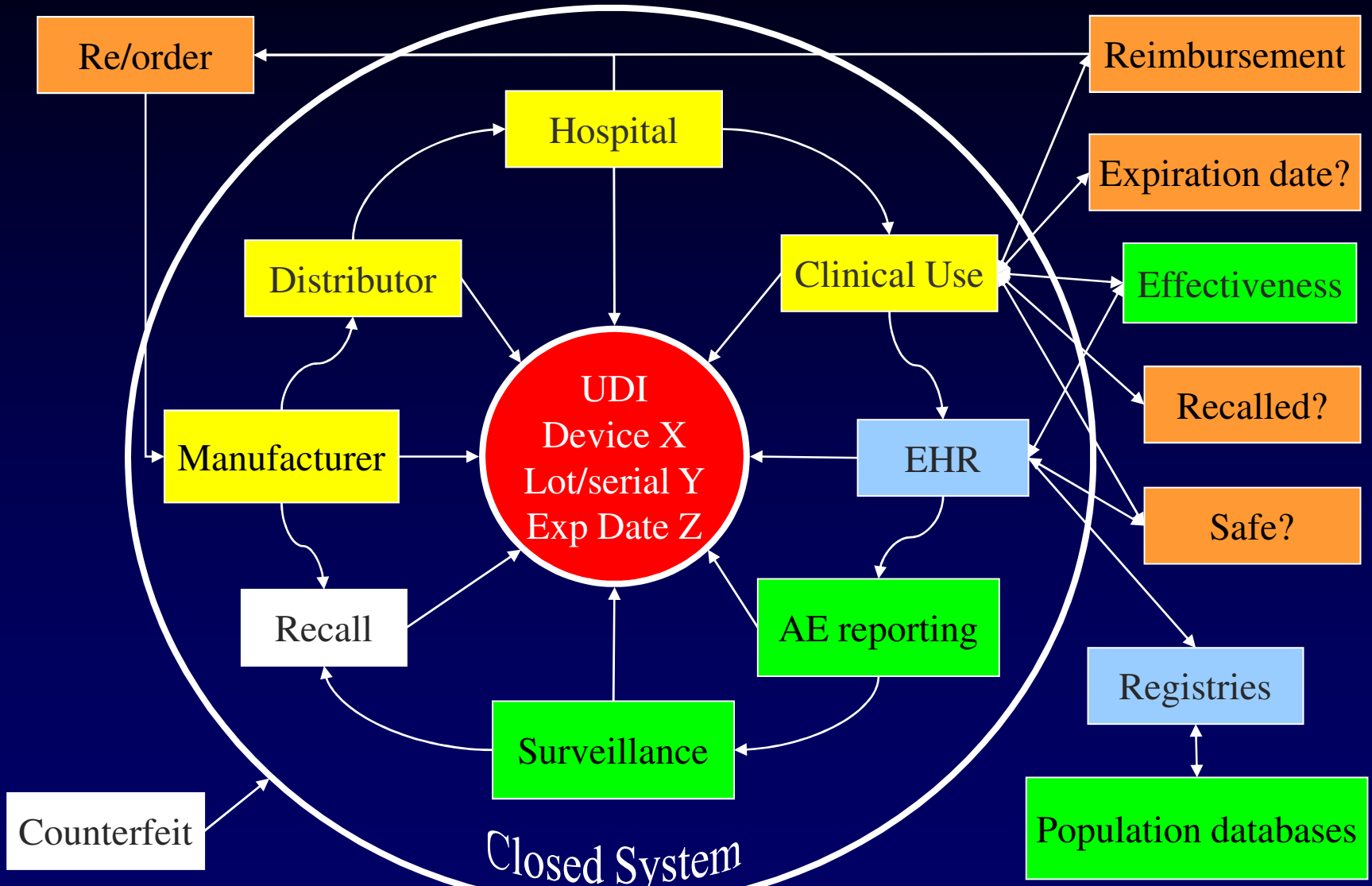
AE Reporting/Surveillance



Recalls


GPOs
Manufacturer
Clinical Substitution
Rentals
Sold
Distributor
Device X
Lot Y
Exp Date Z
Reuse
Direct
Hospital
Physician preference
Recall
Availability
Reorder
Off-master purchase
Clinical Use
Reduce Medical Error
Unit
Sales Rep
Hoarding
Reimbursement
EHR
Population Databases
Postmarket Surveillance
Registries
Clinical effectiveness
AE Reporting
Anticounterfeit
Emergency Preparedness
Cost Effectiveness
Supply Chain Efficiency
Shortage/ Substitution

Future Information Lifecycle



FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

- The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

UDI Public Workshop

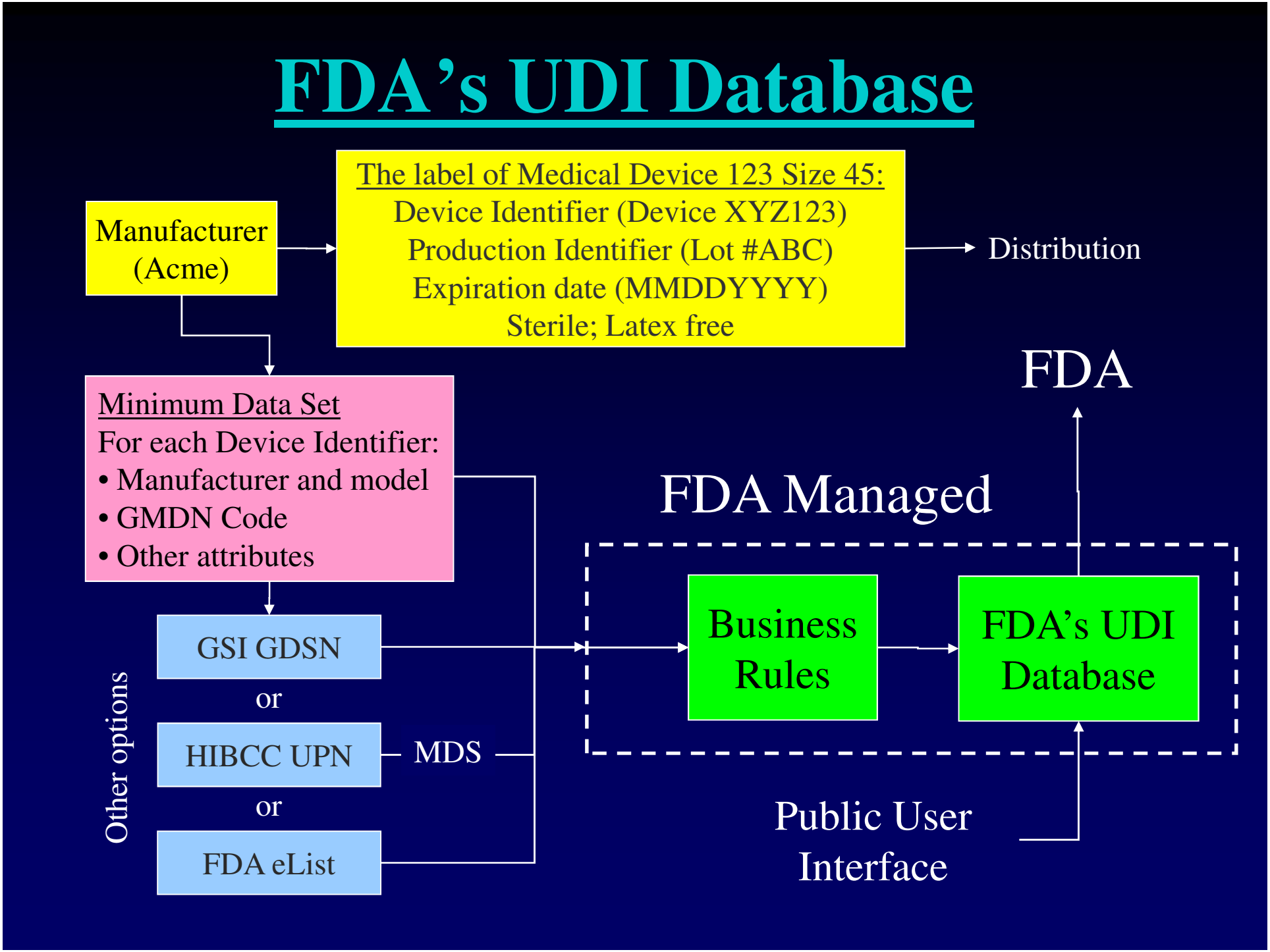
12 February 09 - 300 people attended; 4000 webcast

4 Panels addressed issues related to:

- Developing standardized UDIs
- Placing the UDI in human readable and/or AutoID on a device, its label, or both
- Creating and maintaining the UDI Database
- Promoting adoption and implementation

Received 60 written comments.

FDA's UDI Database



UDI Database Development

- Unique Device Identifier Type/Code [GTIN, HIBICC, NDC]
- Make/model; Brand Name; Long/Short Description
- Unit of Measure/Packaging level/quantity
- Parent/child relationships – e.g., combination product, kits
- Control mechanism – Lot and/or Serial Number; Exp. Date
- FDA Registration number; Contact name, phone, email
- Device status (prescription or over-the-counter)
- US Marketing Authorization Type/Code [e.g., 510K, PMA]
- GMDN Classification code/term
- Country of Origin Code/manufacture/Intended sale
- Storage conditions; Single Use/reusable; Sterility
- Contains known, labeled allergen (e.g., latex)

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation

Adoption and Implementation

- Technology issues/role of technology – barcodes, RFID, DPM
- Distributor uptake and use
- Hospital uptake and use
- Use of UDID
- Medical error reduction (e.g., latex)
- Integration issues – MMIS-Clinical
- EMR$
- Reimbursement
- Privacy

Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

Email: cdrhudi@fda.hhs.gov