Product Authentication and Getting Started With Track & Trace

GS1 HEALTHCARE
TORONTO

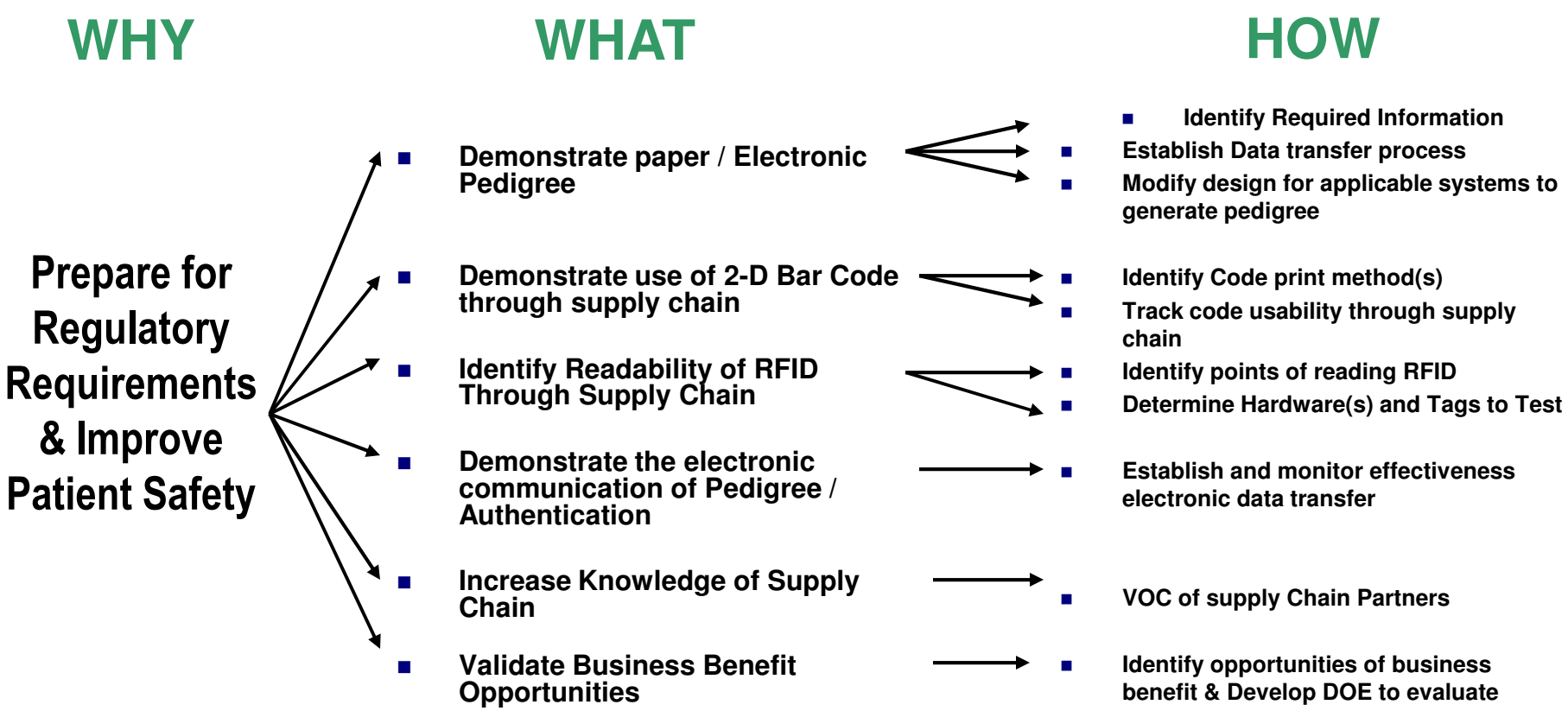
Merck & Co., Inc.

Product Integrity Strategy

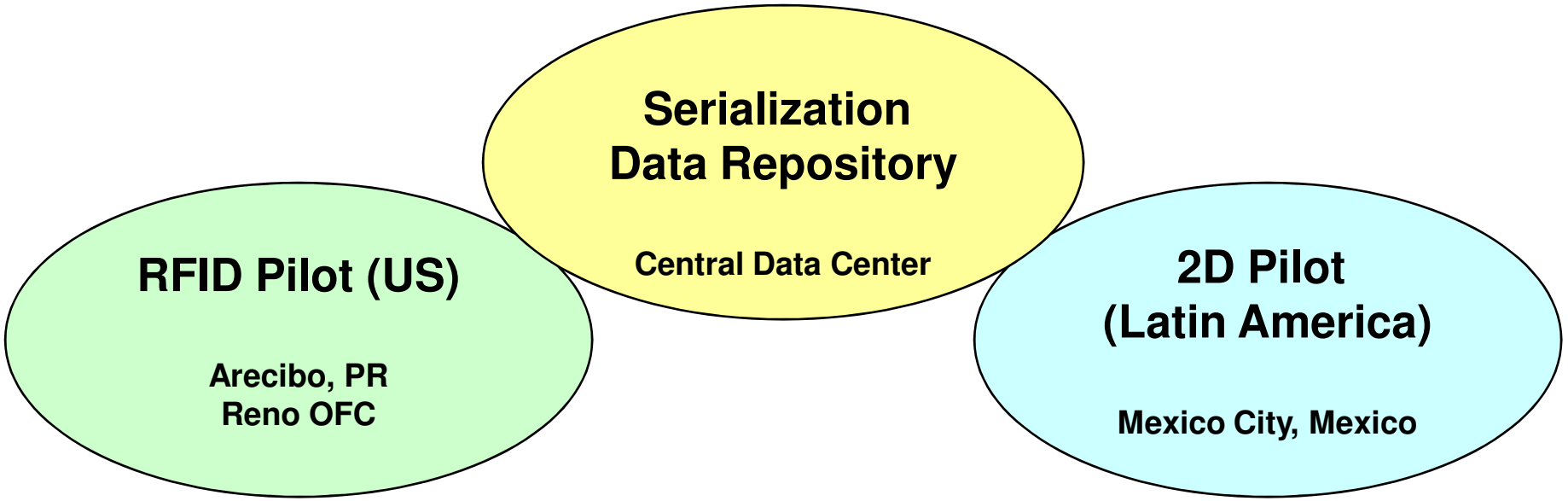
- Why?
  - Patient Safety
  - Compliance
  - Reduce Business Risks
  - Influence future efforts against counterfeits

- What could make up your strategy?
  - Technology (Mass Serialization / Anti-counterfeiting features)
  - Quality (case management / Investigation)
  - Legal (tougher penalties/enforcement)
  - Supply Chain (know trading partners)
  - Public Affairs (how to inform public)
  - Marketing / Sales (awareness / metrics)
  - Security (field Investigations)

Commercial Pilot Strategy



Merck Pilots



Item (Wallet) Level
HF RFID Tag
2D Data Matrix Code

Bundle Level
Virtual Inference

Shipper Level
UHF 2nd Gen RFID Tag
2D Data Matrix Code

Local Data Server
Systech Guardian

Serialized Data Repository
SAP AII

Messaging Exchange
TIBCO

Item (Carton) Level
2D Data Matrix Code
Human Readable Serial Number

Items challenged in Pilot

- Equivalent inlays from manufacturers do not behave the same.
  - Inlays tuned to different frequencies
- Label converters do not convert the RFID labels the same way.
- Multiple brand readers reading the same tag.
- Readability of the 2D data matrix ECC200 code.
- Wallets make it through the complete supply chain.
- Business to Business exchange of data
- Gain experience with centralized serialization repository.

RFID/2D Wallet Label

- 49 x 22mm Removable Label
- Placed on front of wallet
  - Needs to be away from blister
- Pilot RFID/2D label
  - HF UID OTP Tag
    - SGTIN-96 (Item Reference masked)
      - **48.1.6.030006.1000000.123456789012**
    - UID (NXP Serialized Number)
      - **9876543210**
  - 2D Data matrix Barcode (Laser Inverse code)
    - AI(01)+AI(21)
      - **(01)10300060031448(21)123456789012**
  - EPC Global Seal
  - “This label contains a radio frequency device” text

FOSAMAX® RFID Case Label

- 4 x 4 Label on visible size of case near the current shipper end label.
- UHF 2nd Gen Tag
  - SGTIN-96
    - 48.3.6.030006.3003144.123456789012
- 2D Data matrix Barcode
  - AI(01)+AI(21)
    - (01)30300060031442(21)123456789012
- Linear GTIN Barcode 128
  - AI(01)
    - (01)30300060031442
- Linear Serialized Barcode 128
  - AI(21)
    - (21)123456789012
- Human Readable SGTIN-96
- EPC Global Seal
- “This label contains a radio frequency device” text

Pilot Findings To-Date

- Serialization is not a turn key solution.
- Little changes can greatly effect RFID performance.
- Standards gaps & options allow for mixed practices.
  - Limited interoperability of reader brands
  - Data formats
  - Reader to tag readability
  - Alignment with supply chain partners
- Strong business practices are critical for success.
- Robustness of systems is still a concern.
- Key Suppliers in Industry have or could have capacity gaps.
- Integrity of Inference requires well designed systems.

Key Findings During Packaging

- With a well designed system, similar line performance is possible.
- When a system goes off-line, everything stops!
- Process must be designed to detect manual errors/atypicals
  - Visuals and training to reduce mental stress of operators
  - Virtual Accountabilities vs. Physical Accountabilities differences.
  - Materials are found out-of-process, which causes discrepancies.
- Robustness of systems still needs improvement to sustain product supply.
  - Issues have been seen during production that caused discard of physically good material.
  - Maintaining communication with all the systems.
- As expected, not all RFID labels behaved the same way.
- Identified additional improvements to the line and processes for full scale serialization.

Packaging Line Read Rates