



SToP Project in the Pharmaceutical Industry

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Zurich - May 27, 2009



- Business Drivers & Regulatory Situation
- What Track & Trace means in Practice
- Business relevance of SToP
- Contributions to SToP
- SToP Results
- Pharmaceutical Industry Outlook



- In 2004 the U.S. FDA issued a white paper recommending the use of RFID for serialization of sales packs
- California government had mandated mass serialization and product tracking of all sales packs for prescription drugs
 - High pressure for compliance through deadline of Jan 2009
 - Driver: Anti-counterfeiting
- Only evolving standards and technology solutions
 - Data carrier: RFID (HF vs. UHF gen2) or 2D Datamatrix Codes
 - Lack of proven solutions re. integration of serialization and tracking into packaging lines, distribution processes and local and global IT systems
 - Lack of IT systems to handle serialized product data as well as other product security features e.g. holograms
- In general manufacturing and distribution processes of pharmaceutical products are highly regulated and require minute documentation when installing any system



Globally increasing Regulatory Discussion

Mass Serialization and Product Tracking



Drivers for Implementation

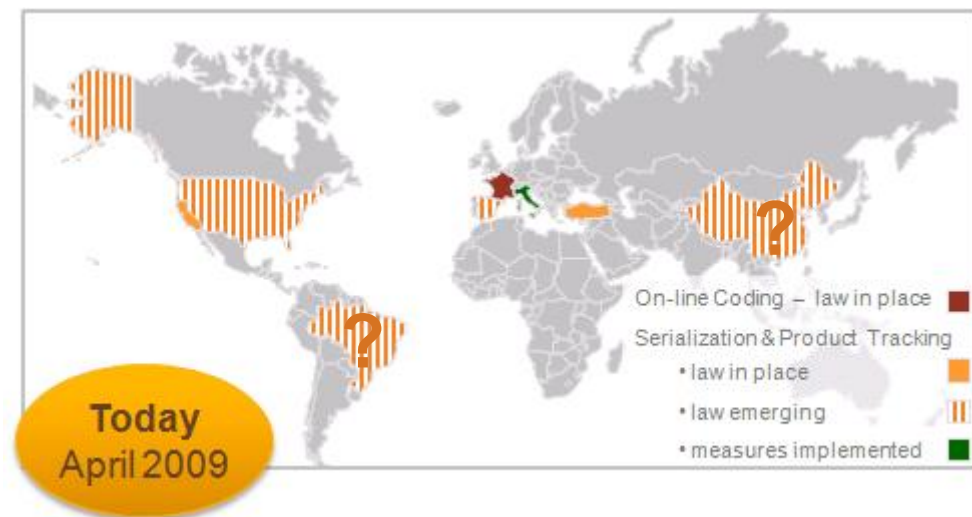
- Enhance Patient Safety
- Raise barrier against counterfeits
- Combat Reimbursement Fraud

Past: Lack of standardized Solutions

- Italy 2005: local serialization solution implemented, tracking pending
- California 2009: e-Pedigree Law postponed to 2015

Today: 1st Harmonized Requirements

- Turkey 2009: 2D data matrix serialization, tracking Jun 2010.
- France 2011: 2D data matrix coding
- Regionally harmonized regulations are drafted in U.S. and EU respectively
- Emerging markets mandating or drafting regulations for mass serialization & product tracking: Brazil & China



What it means in practice...

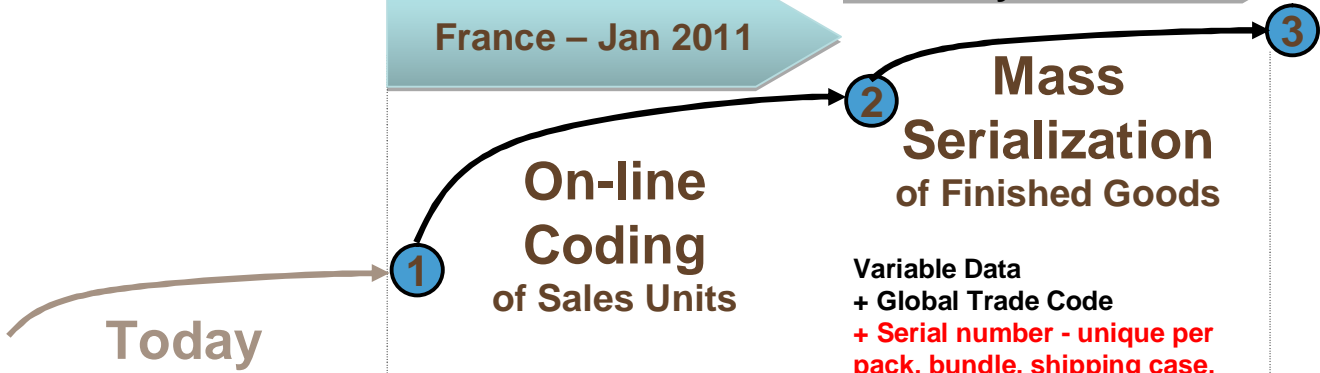
Mass Serialization & Product Tracking



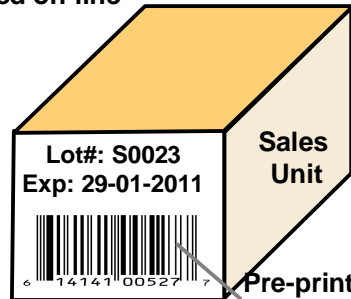
Turkey – Jun 2010, California – Jan 2015/ Jan 2016

Turkey – June 2009

France – Jan 2011

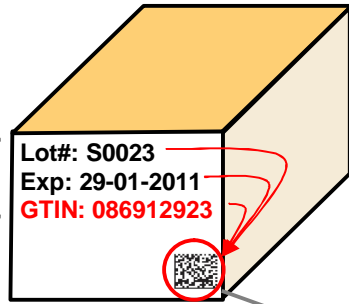


Human Readable Variable Data embossed or printed on-line



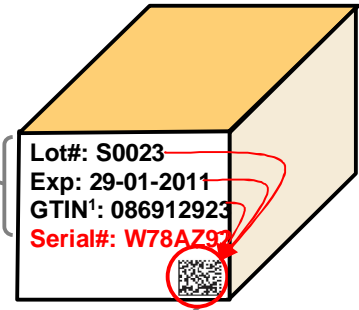
Pre-printed local Trade Code (by supplier of packaging material)

Human Readable Variable Data printed on-line + Global Trade Item Number GTIN

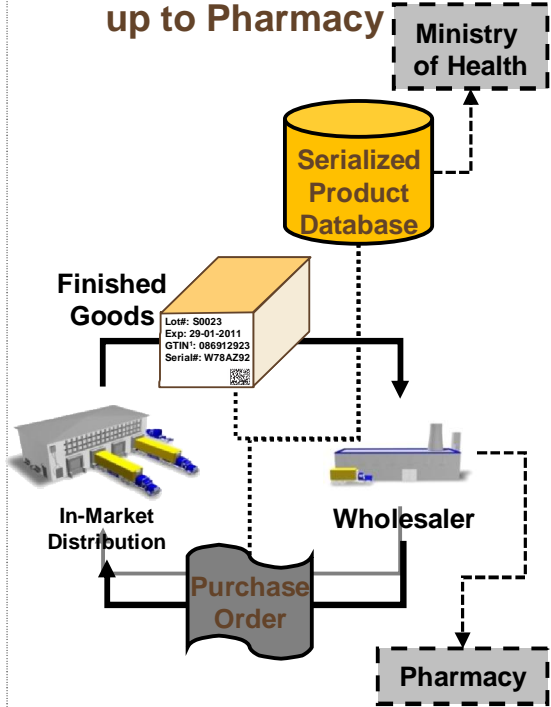


In addition, same data encoded + verified online

Variable Data + Global Trade Code + Serial number - unique per pack, bundle, shipping case, pallet



Product Tracking up to Pharmacy



Business Impact

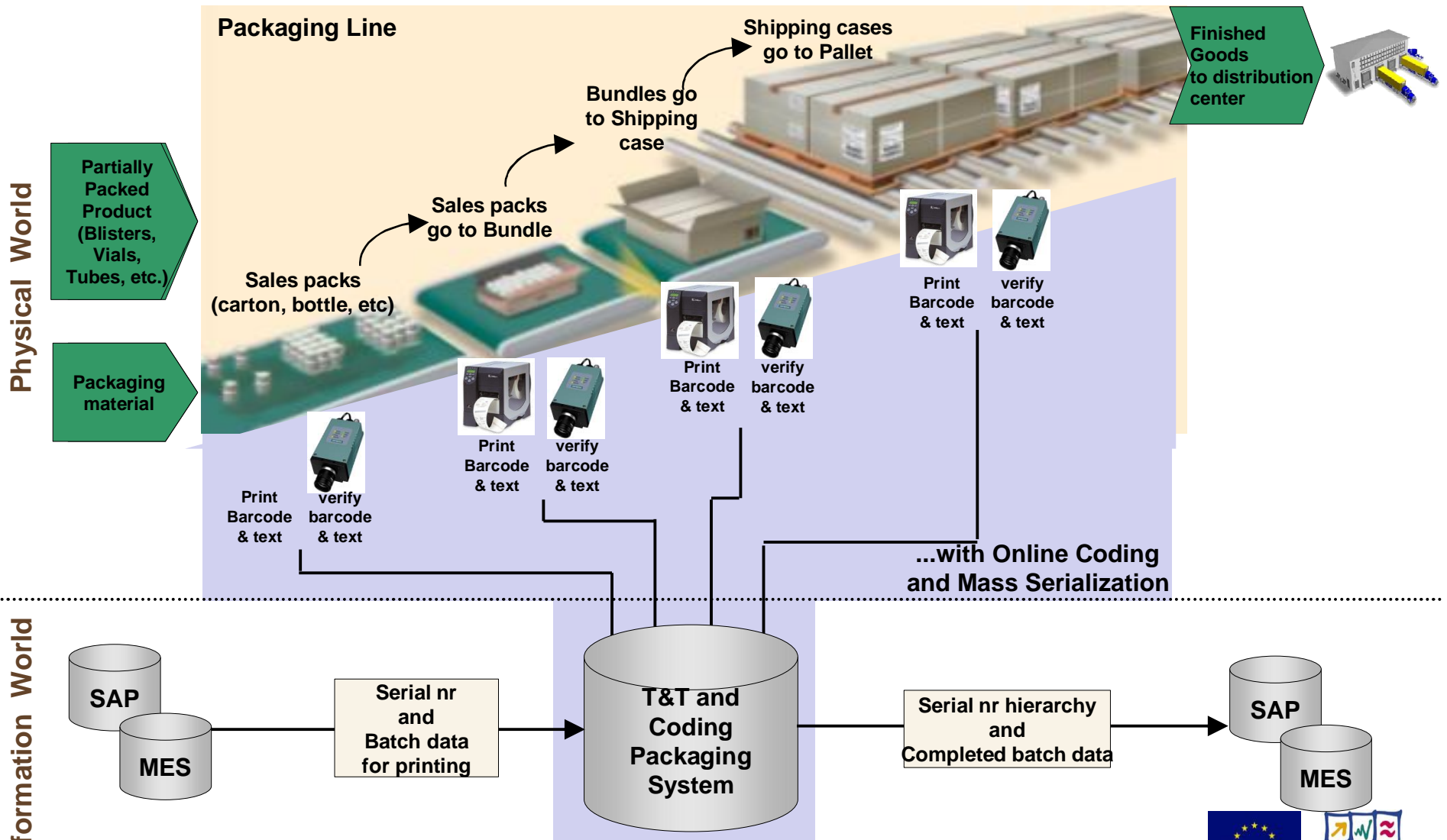
Packaging Site

Distribution Center



Packaging Lines: Upgrade required

Mass Serialization of all Packaging Hierarchies

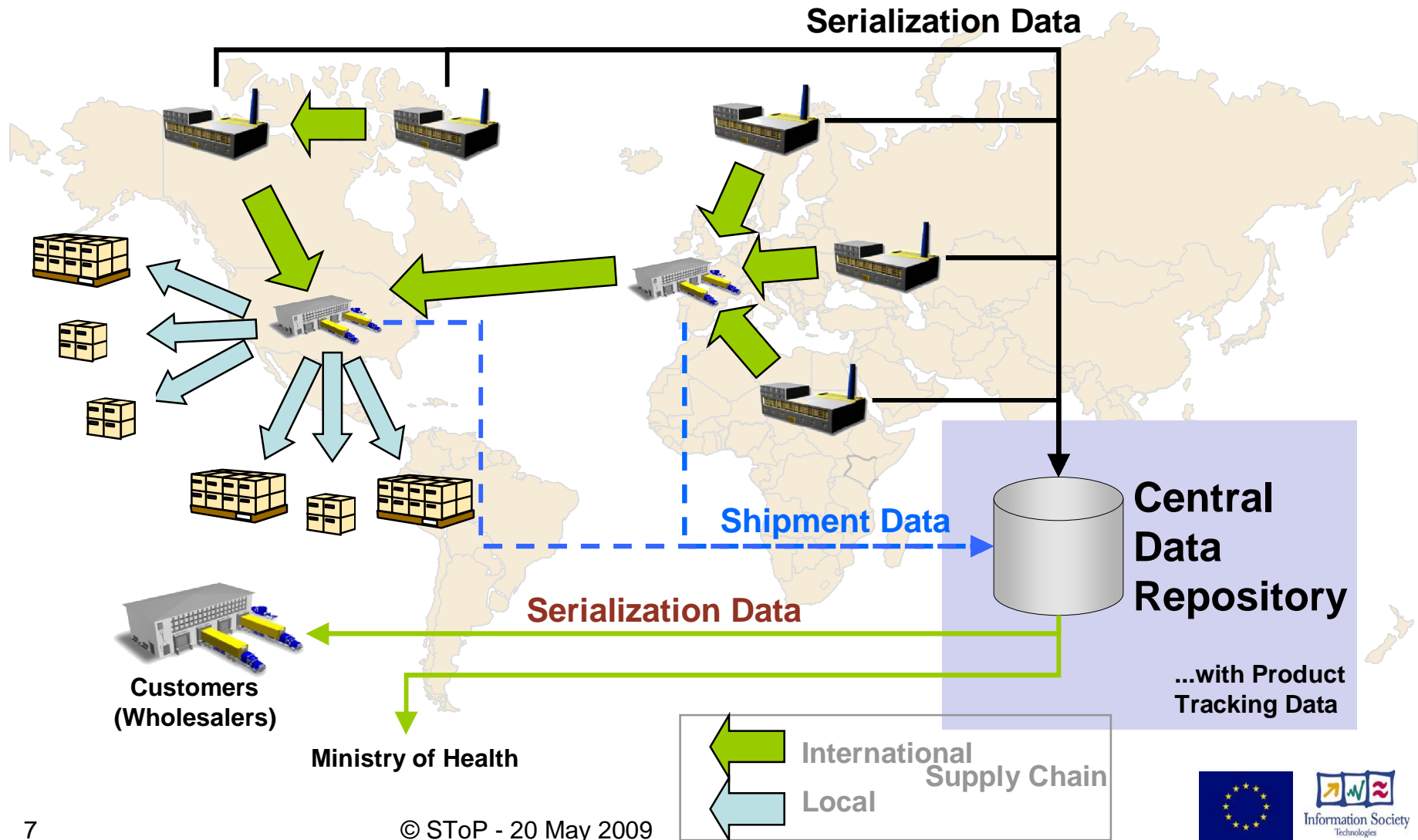


Information World



Distribution: New Processes required

Tracking product from Production Site to Wholesaler





- Business motivation when joining SToP project in 2006...
 - enable best-practice sharing regarding product security with academia, aerospace, security printing and luxury goods, solution providers.
 - drive a fact-based selection of the most appropriate RFID technology for serializing pharmaceutical sales packs
 - support a business decision of RFID vs. Datamatrix serialization
 - explore the practical relevance of RFID vs. Datamatrix to the end-user (pharmacy trials)
 - ensure that future product verification systems would be suitable for pharmaceutical production and distribution

- Share industrial experience of mass serialization in packaging and distribution of an industrial scale implementation that was established independently of SToP



- Active contribution through...
 - details regarding **mechanisms of counterfeiting trade** within the Pharmaceutical Industry
 - **identifying the most appropriate RFID technology** for serializing pharmaceutical sales packs through laboratory trials - mimicking the packaging process of pharmaceuticals
 - formulating the **requirements for a Product Verification Infrastructure (PVI)** intended for the Pharmaceutical Supply Chain whilst ensuring that future systems are addressing all business needs
 - producing **mass serialized placebo product** (RFID tags & data matrix codes) to test the PVI.
 - exploring the **practical relevance** of RFID & Datamatrix to the end-user
 - **sharing best-practices** with key interested stakeholders (EFPIA)
 - analyzing the ongoing industrial runs to **drive a fact-based business decision of RFID vs. Datamatrix serialization**



- Video showing the operational pilot of packaging serialized pharmaceutical products



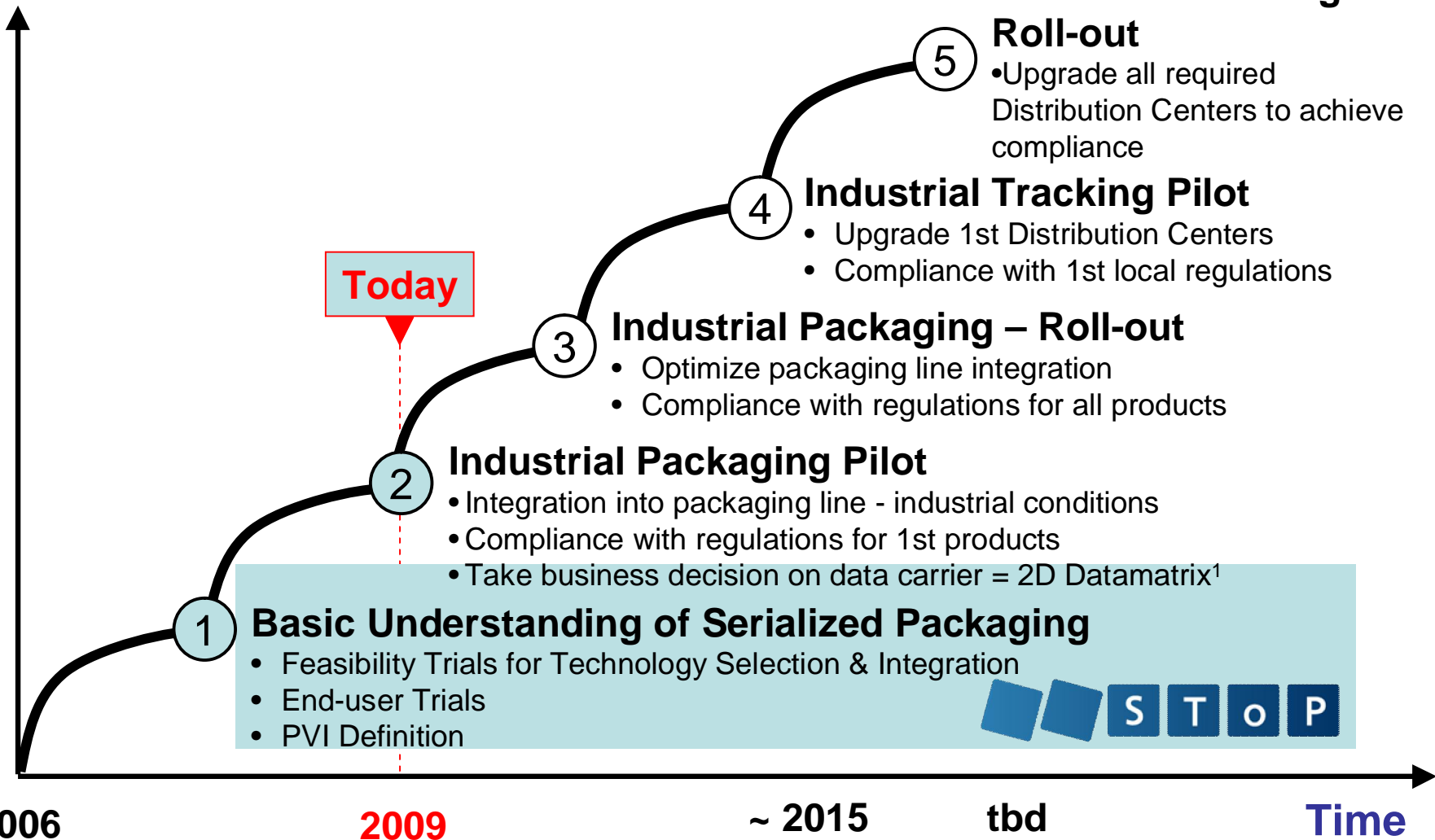
- The STOP work helped to shape implementation strategy for unique serialization and product tracking of pharmaceutical goods – an implementation program that will continue for the next 10 years to come
- STOP trials with end-users identified Issues regarding print quality of Datamatrix codes and artwork layout.
 - Technical requirements for future implementations were improved
 - Issues and corrective actions were communicated to other pharmaceutical companies within the EFPIA (European Federation of Pharmaceutical Industries and Associations).
- STOP activities helped to adjust technical requirements for Product Verification Infrastructures (PVI)

Pharmaceutical Industry Outlook

Capability Roadmap



Capability



¹ Results to be published





Thank you.
Any Questions?

Matthias Pfletschinger

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Novartis Pharma AG



Serialization of Pharmaceutical Products

SToP Project Results

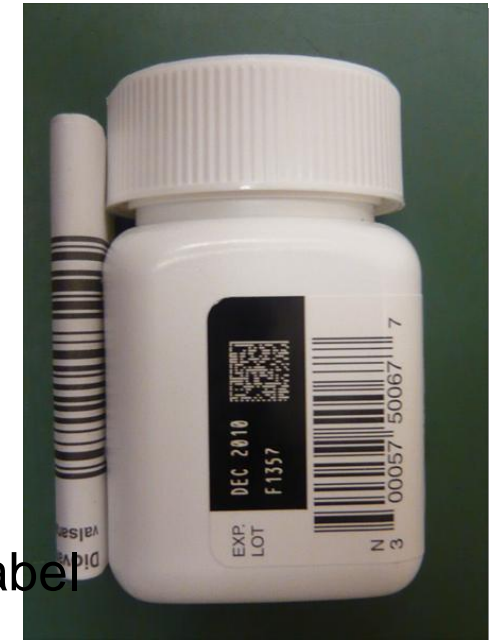


■ Scope: Tablets in Plastic Bottles

- No liquids
- No aluminum contained in packaging material

■ Data Carrier

- 2D Datamatrix
- RFID UHF Gen 2 integrated into the bottle label
- Rejected: RFID HF



■ Process: On-line encoding on packaging line at 250 packs p. min

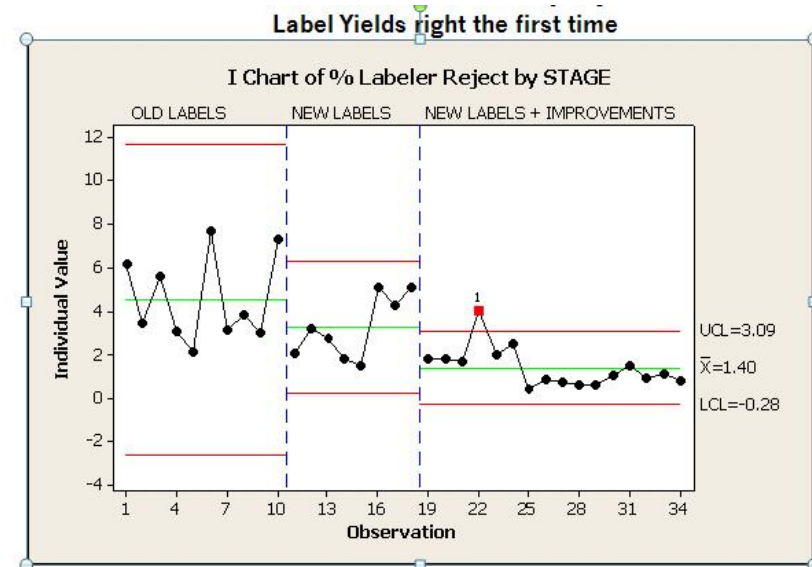
■ Results

- Operational since January 2008
- ~250'000 Packs serialized

Industrial Results of Serialized Pharmaceutical Products



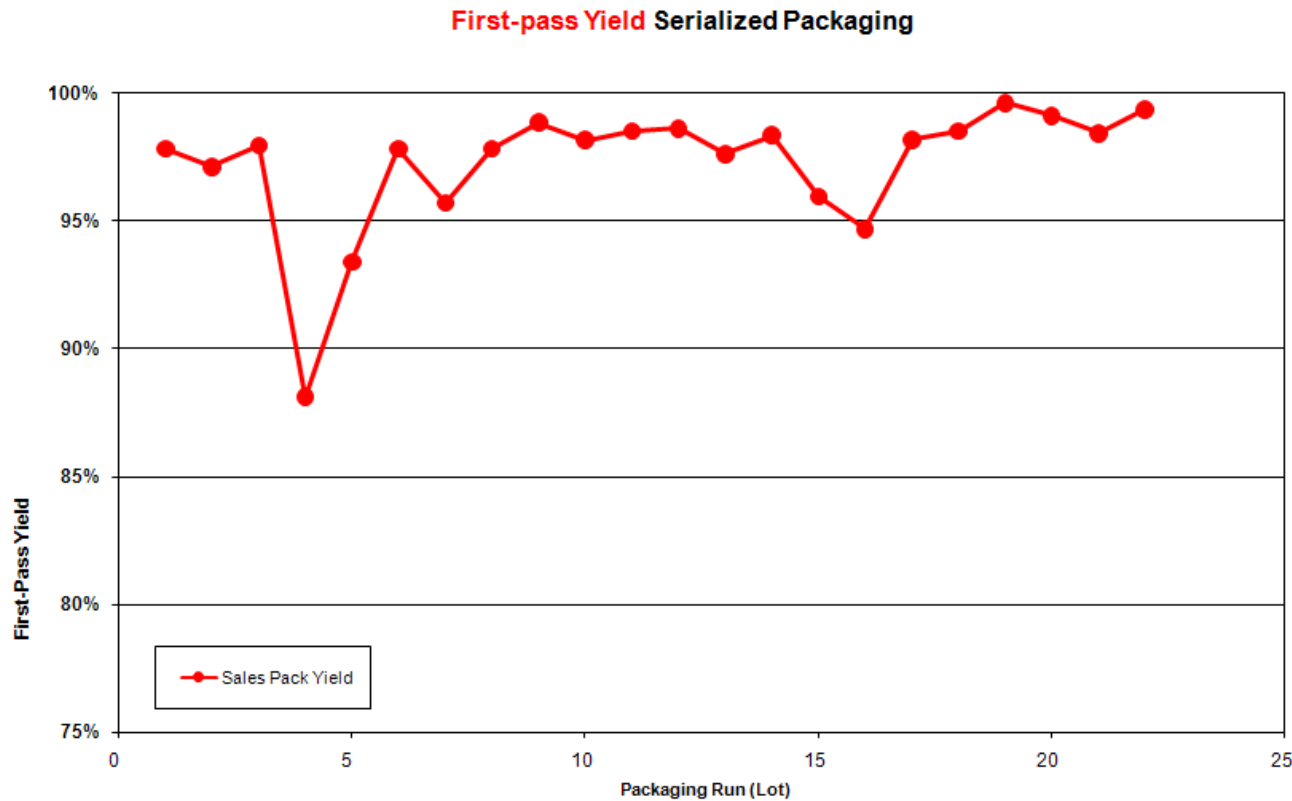
1. RF implementations are unique per packaging line
 - Different dosage forms & packaging materials in pharmaceuticals require different RF frequencies (+ readers): aluminum, glass, liquids
 - Different installations of existing hardware
 - Unique situation regarding RF interference & RF shielding
2. Managing RFID label quality is a challenge: Three suppliers contribute to the final result
 - Tag producer
 - Inlay producer
 - Label Converter



Industrial Results of Serialized Pharmaceutical Products - *continued*




3. Still unacceptable reject rate when producing serialized packs
- Directly after go-live: 12% or equivalent to 30 packs per minute
 - After >20 lots: Ø 2.2% or equivalent to 5 packs per minute



Selection of Data Carriers

GS1 2D Datamatrix Standard has emerged as standard for sales pack coding within the healthcare industry



	RFID	2D Datamatrix 	Linear / Stacked Barcode
Available Standards	<ul style="list-style-type: none"> LF – Low Frequency HF – High Frequency UHF – Ultra High Frequency 	<ul style="list-style-type: none"> GS1 ISO 	<ul style="list-style-type: none"> GS1
Situation	<ul style="list-style-type: none"> Frequency bands not harmonized globally No single solution available that covers all requirements (e.g. liquids, solids, metal) 	<ul style="list-style-type: none"> GS1: Some minor details regarding hierarchy building still open ISO: Focus on automotive industry 	<ul style="list-style-type: none"> Technical disadvantages compared to 2D (high space requirements on packaging material)
Adoption	<ul style="list-style-type: none"> Even within one market multiple standards are used Limited outside U.S. No legal requirement to date 	<ul style="list-style-type: none"> GS1: required by law in Turkey, EFPIA, France, Spain, Serbia GS1: regul. discussion: Germany, Italy, Brazil, California 	<ul style="list-style-type: none"> Required by law in Japan, Belgium, Italy, S. Korea Regulatory discussion: China
Conclusion	<ul style="list-style-type: none"> Currently too expensive Performance requires further improvements Still hurdles to wide-spread adoption 	<ul style="list-style-type: none"> GS1 standard receives support by more & more legislations Solution of Choice 	<ul style="list-style-type: none"> Line hardware for 2D is able to handle linear & stacked barcodes Investment into 2D covers these requirements as well

- Approach: Use uniquely serialized pharmaceutical product for a point of sale verification in two Pharmacies (2D Datamatrix Code & RFID UHF Gen2)

- Results

1. Quality issues with reading of 2D datamatrix code

- Reason A: Low resolution of point of sale code readers compared to industrial high-resolution cameras
- Recommendation A: Print quality of 2D code must be increased on the packaging line – Grade C or better as per ISO/IEC 15415.
- Reason B: Barcode readers in the pharmacy confused the pre-printed linear barcode and the 2D datamatrix code as both codes were physically close to each other.
- Recommendation B: Do not place linear barcodes and 2D barcodes next to each other on the packaging material



2. Pharmacy staff preferred RFID over 2D Datamatrix
 - Further tests are required to confirm readability for liquid drug substances & product with metallic packaging components.
3. SAP Prototype of the Product Verification Infrastructure (PVI) was able to manage data storage and point of sales verification for multiple product security features.





- Business Issue: Enable fast verification of suspect samples in the market based on multiple levels of product verification features, like...
 - Unique serial numbers per sales pack
 - e.g. Copy detection pattern
 - e.g. Holograms
 - ...

- With the Product Verification Infrastructure (PVI) the consortium partner SAP demonstrated successfully the technical feasibility of such a system
 - Open question: Availability of standard IT system