



GS1 Colombia

Traceability HealthCare Pilot

CABASnet STL

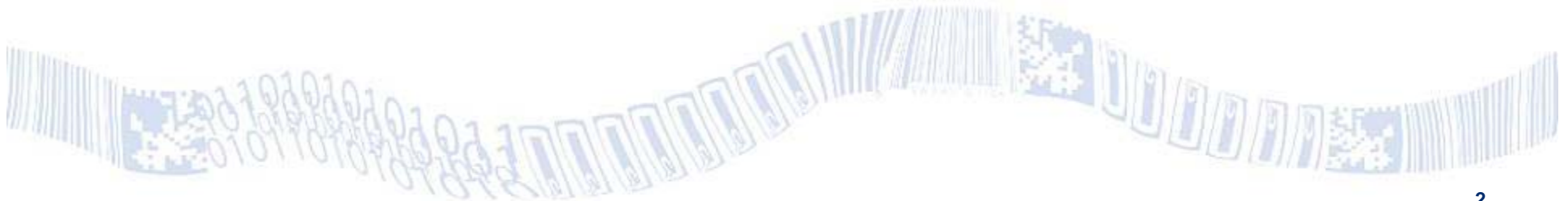
São Paulo, Brazil
March 16, 2010





Agenda

- GS1 Colombia - Introduction
 - Local Work Group
 - CABASnet STL Pilot
- PFIZER CONSUMER HEALTHCARE
 - Background
 - Product & Information Flow
 - Phase I Lot Number Tracing
 - Conclusions
 - Next Steps





Our Work in Colombia, With and for Users

Laboratories / Suppliers

- 3M COLOMBIA
- ABBOTT LABORATORIES DE COLOMBIA
- EXPOFARMA
- GRUPO SOCIAL PROHANT INTERNATIONAL
- INDUSTRIAL FARMACEUTICA UNION DE VERTICES DE TECNOFARMA S.A
- JOHNSON & JOHNSON
- LABORATORIOS ECAR S.A.
- WYETH CONSUMER HEALTHCARE LTD (Now Pfizer Consumer Health Care)
- GLAXOSMITHKLINE
- LABOR

Retailers and Wholesalers

- CAFAM
- COLSUBSIDIO
- COMFANDI
- ALMACENES ÉXITO
- COPIDROGAS
- DROMAYOR
- ATORIOS ALCON

Solutions Providers

- ADT IS
- CIBERGENIUS
- EGOMEXICO
- INTELIGENSA
- QUIMBAYA
- SIRIT
- TECPOINT





Local Work Group Activities

Since the emission of the 1403 Resolution of the Healthcare Ministry, the Local Work Group re-schedule activities:

2008, September 15: First Meeting Local Work Group

2008, Sept. 23: Making Document for HealthCare Ministry

2008, November 14
Meeting with the HealthCare Ministry, Associations and GS1 Colombia

2008, December 23
Proposal for elaboration of the work schedule to design a Traceability System for HealthCare Sector in Colombia

2009, February 11 and 25
Presentation Proposal Stages of Pilot
-Start Pilot – Stablishment Groups

2009, June 17. First Results
-Methodology
-Learning

2009, Decembre 9. Presentation of the first draft of a Local Traceability Standard Healthcare Implementation Guide supported on the GTSH



Traceability Pilot Scope

Deploy along value chain healthcare sector an efficient and effective Traceability Model for medicines, pharmaceutical products, medical devices and surgical instruments supported by the **GS1 System** that ensures the safety of the patient and/or Final Consumer and to contribute to the efficiency and competitiveness of participants organizations.





Traceability Pilot Stages

- **Stage I >> Traceability using Bar Codes No Serialization** – Consumer Unit, supported by CABASnet STL

Laboratories	Wholesalers	Retail (Pharmacies)
Tecnofarma		Colsubsidio
Wyeth Consumer		Cafam
Laboratorios Alcon	Dromayor	Droguerías Superpharma
Wyeth Consumer		Almacenes Éxito

- **Stage II >> Technical Evaluation and implementation of Traceability for pallets, cases, some consumer units and medical devices using GS1 DataMatrix and/or EPC / RFID**





CABASnet STL - Online Traceability System

System which allows to the healthcare value chain actors to register, to interchange and to consult on line static and dynamic traceability information about every product identified with a GTIN.





Premises

- Platform non - dependable of the internal system information of the actor
- Integrated and Supported by CABASnet Synchronization
- Future Capability for integration with other solutions like **CABASnet Sales and Inventory Data** and **EPCIS** (Electronic Product Code Information Service)
- Scalable solution GTIN13 >> DATABAR / DATAMATRIX >> EPC



Multiple Means of Online Search

Authentication



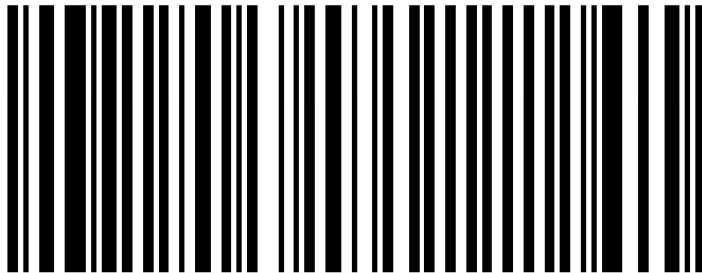
Main Features

- Static >> Synchronisation (description, image, manufacturer, etc.)
- Dynamic >> Deliveries, dates, lots and expiration dates





Main Features



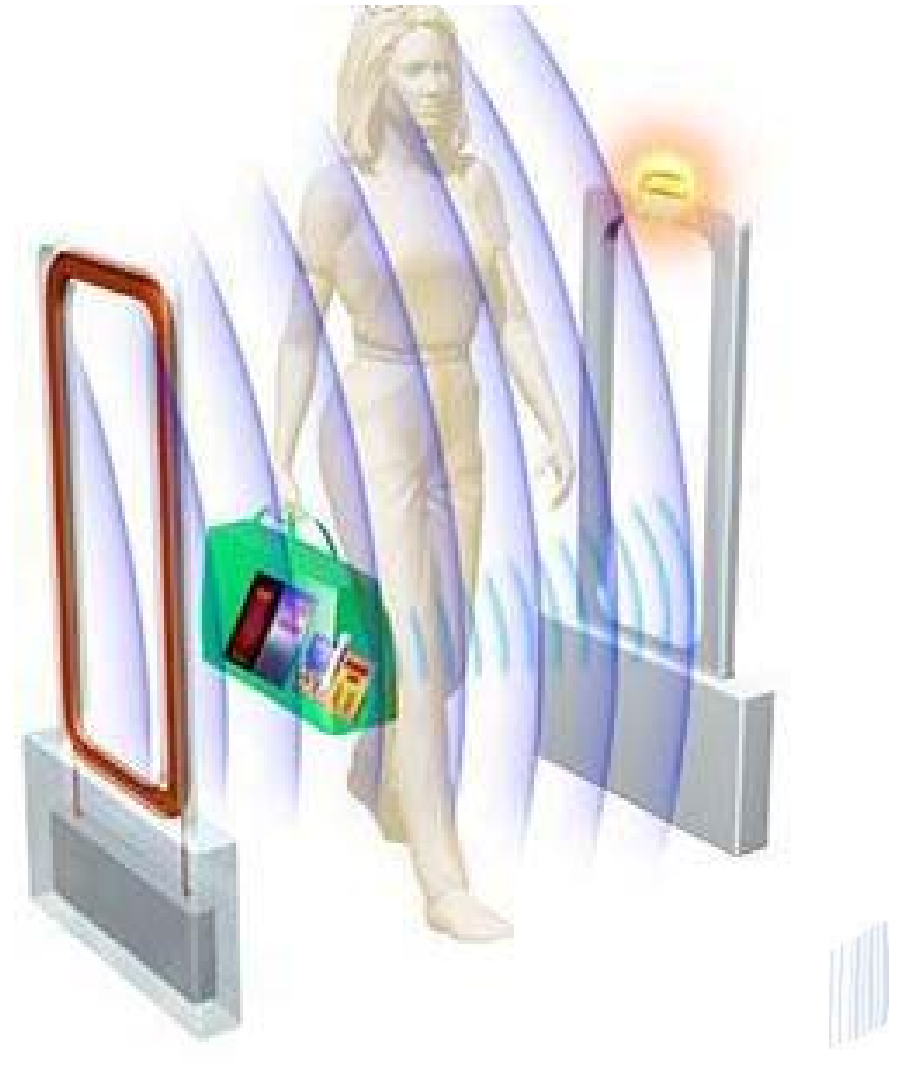
(01)1770123400001

Query Criteria

- CUM, Unique Medical Code
- GTIN / SERIAL

Main Features

Alerts: Lots, Sanitary Registers
and expiration dates





Generation and report download

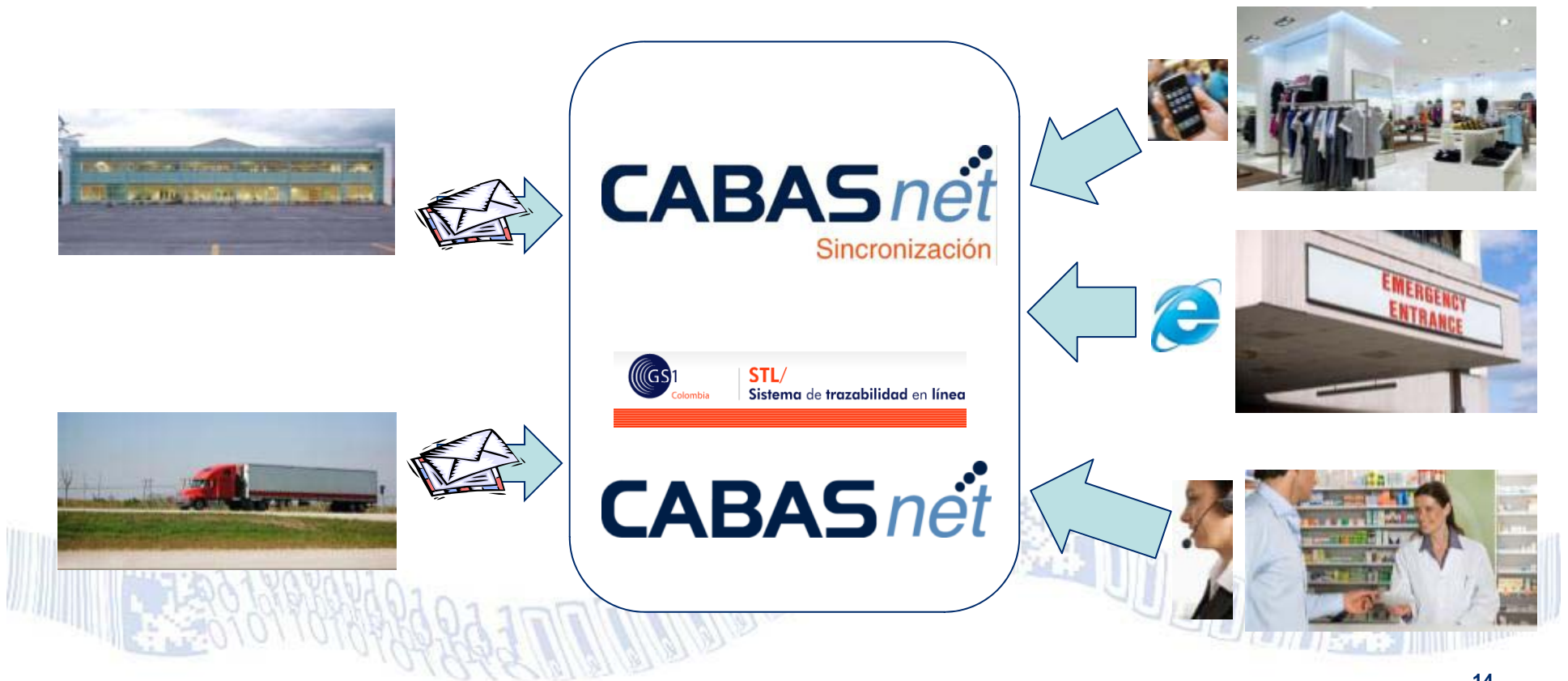
Información del Producto

FABRICANTE	Monteverde
DESCRIPCION	Clozapina x 20 compri. x 100 mg
MARCA	TECNOFARMA
FORMA FARMACEUTICA	Comprimidos
CANTIDAD CONTENIDA	20 Numero de artículos
CUM	482273
REGISTRO SANITARIO	INVIMA 2005M003812R1



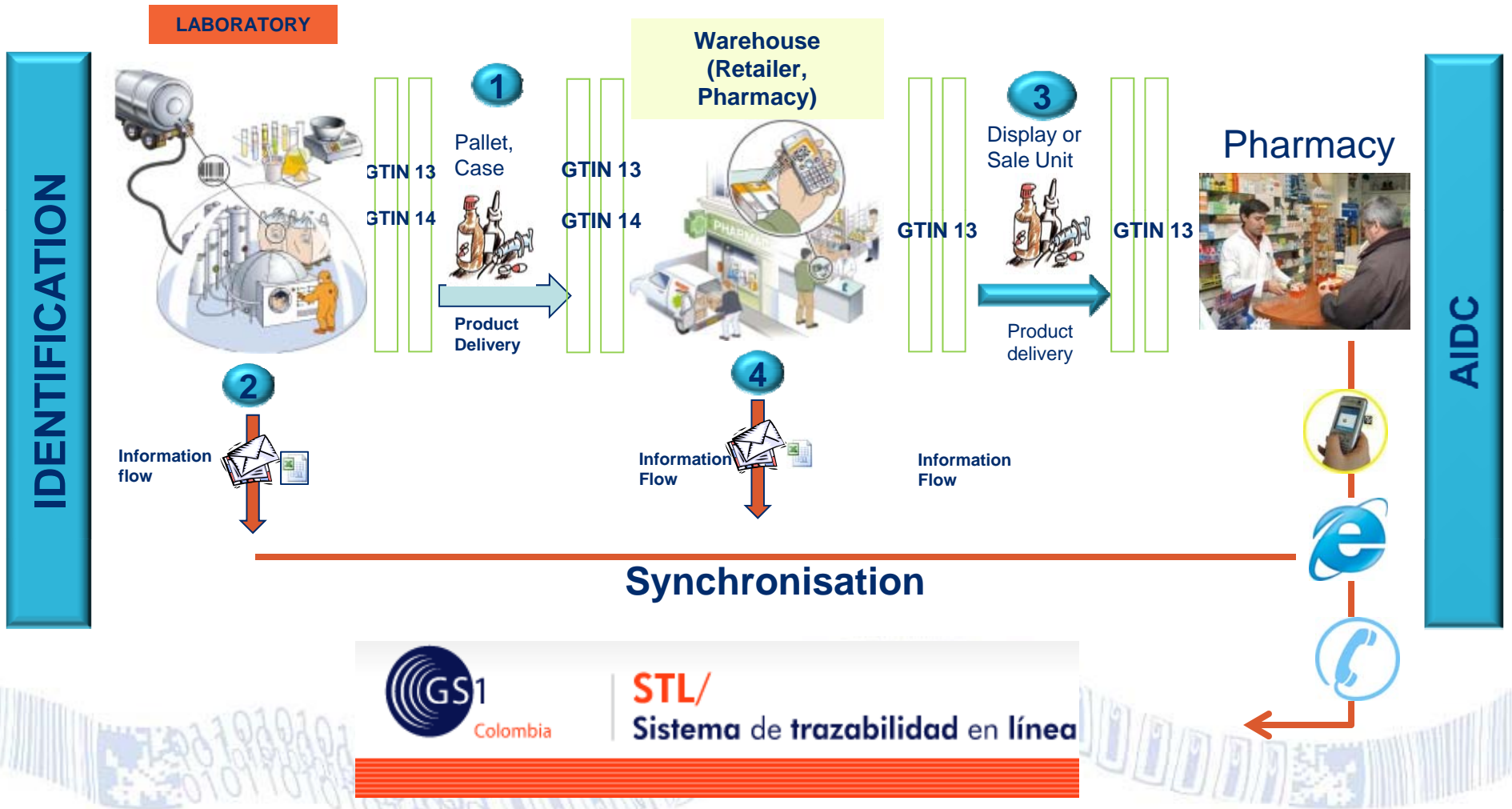
Main Features

Storing and Centralized information – Confrontation of the information printed on the product versus the originally reported by the owner of the product

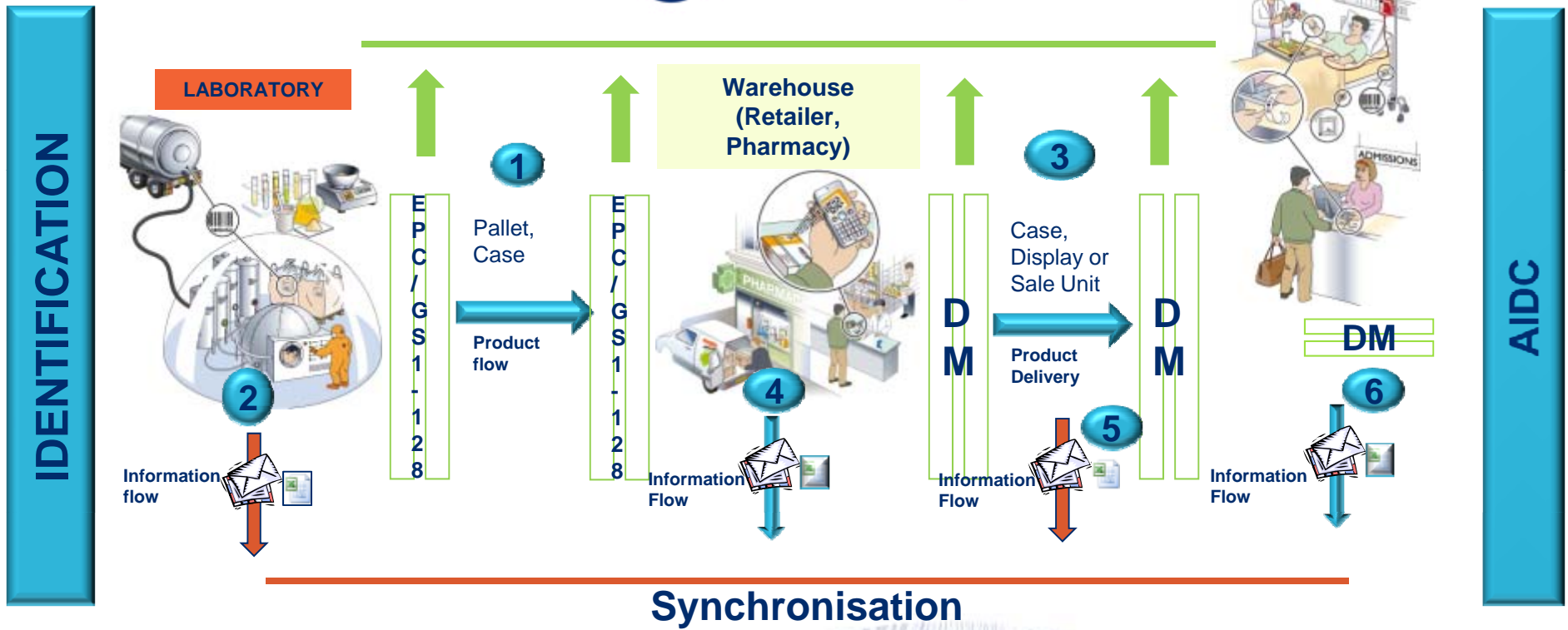


Product and Information Flow

Actual Scenario



Product and Information Flow Ideal Scenario



DM= DATAMATRIX




STL/
Sistema de trazabilidad en línea


STL

Consulta de Trazabilidad

- ↓ Inscripción
- Consultas
 - ↳ Consulta Trazabilidad
- ↓ Administración
- ↓ Reportes

Haga click en el boton lupa para acceder a las opciones de busqueda

Busqueda por producto 

Busqueda por lote 

Información del Producto

Foto del Producto

GTIN	7702132004392
FABRICANTE	Procaps s.a.
DESCRIPCION	Advil fastgel x 20 cap.
MARCA	ADVIL
FORMA FARMACEUTICA	Capsulas
CANTIDAD CONTENIDA	20 Numero de artículos
CUM	
REGISTRO SANITARIO	2002M-0001491





Traceability through CABASnet STL

Información de Trazabilidad

Transacción desde el Nodo A hasta el Nodo B

A

ORIGEN 770213200011
WYETH CONSUMER HEALTHCARE LTD.
AUT. CALI YUMBO KM. 2

FECHA DESPACHO 01/01/1900

LOTE 8113773

CANTIDAD 1

FECHA DE FABRICACION

FECHA DE VENCIMIENTO 31/10/2010

B

DESTINO 7701011020508
DEPTO DISTRIBUCION
CLL 23 68C-85

NODES

Transacción desde el Nodo B hasta el Nodo C

B

ORIGEN 7701011020508
DEPTO DISTRIBUCION
CLL 23 68C-85

FECHA DESPACHO 17/06/2009

LOTE 8113773

CANTIDAD 2

FECHA DE FABRICACION 01/11/2008

FECHA DE VENCIMIENTO 01/10/2010

C

DESTINO 7701011023035
DROGUERIA FLORESTA 24 HORAS
AV. 68 No. 92-30

Ubicación actual del Nodo C

C

ORIGEN 7701011023035
DROGUERIA FLORESTA 24 HORAS
AV. 68 No. 92-30

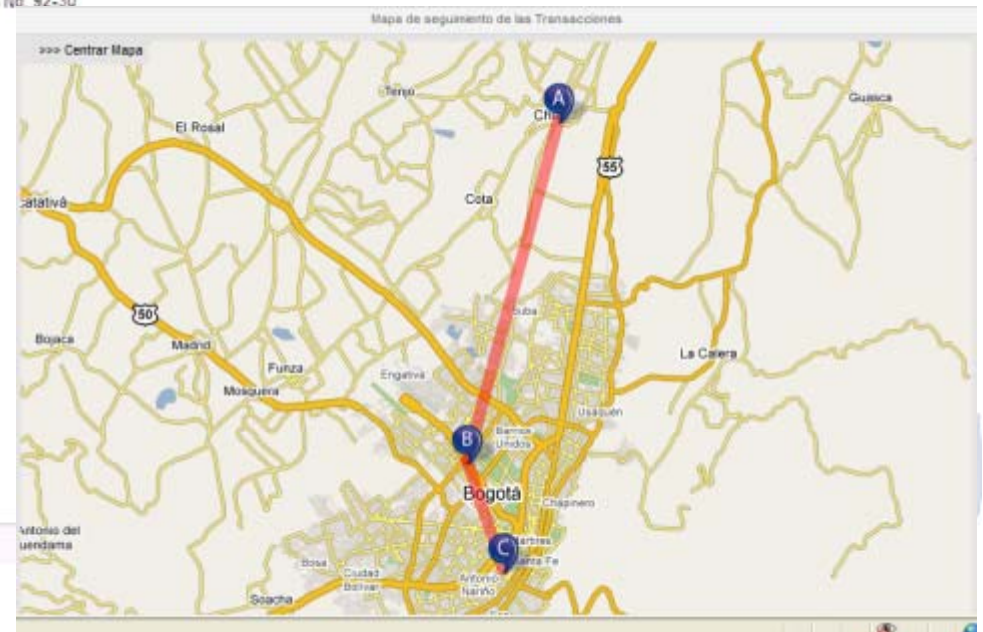
FECHA DESPACHO 17/06/2009

LOTE 8113773

CANTIDAD 2

FECHA DE FABRICACION 01/11/2008

FECHA DE VENCIMIENTO 01/10/2010



[Ver Mapa](#)

Geographic position



CABASnet STL Pilot



STL/
Sistema de trazabilidad en línea

- Users:26
- Transactions: 10.844
- Single batch: 1.634
- Processed Documents : 99
- Locations: 106

Benefits and learning

- Achieving short term results
- Instead using CDs, Printed Documents and other means, the choice was Standardized Electronic Information Interchange.
- Centralization and on line access to the information
- In the Point of Sale, verification to accept devolutions from consumers
- Specific control for each batch and product in the locations
- Inventory management supported by expiration dates
- Standard is cheaper than other solution (holograms, oter codes, etc)
- DataMatrix and EPC should be the next steps



Collaboration Produces Results



Implementing a Traceability System for Pharmaceuticals and Medical Devices in Colombia.

São Paulo, Brazil

March 16, 2010



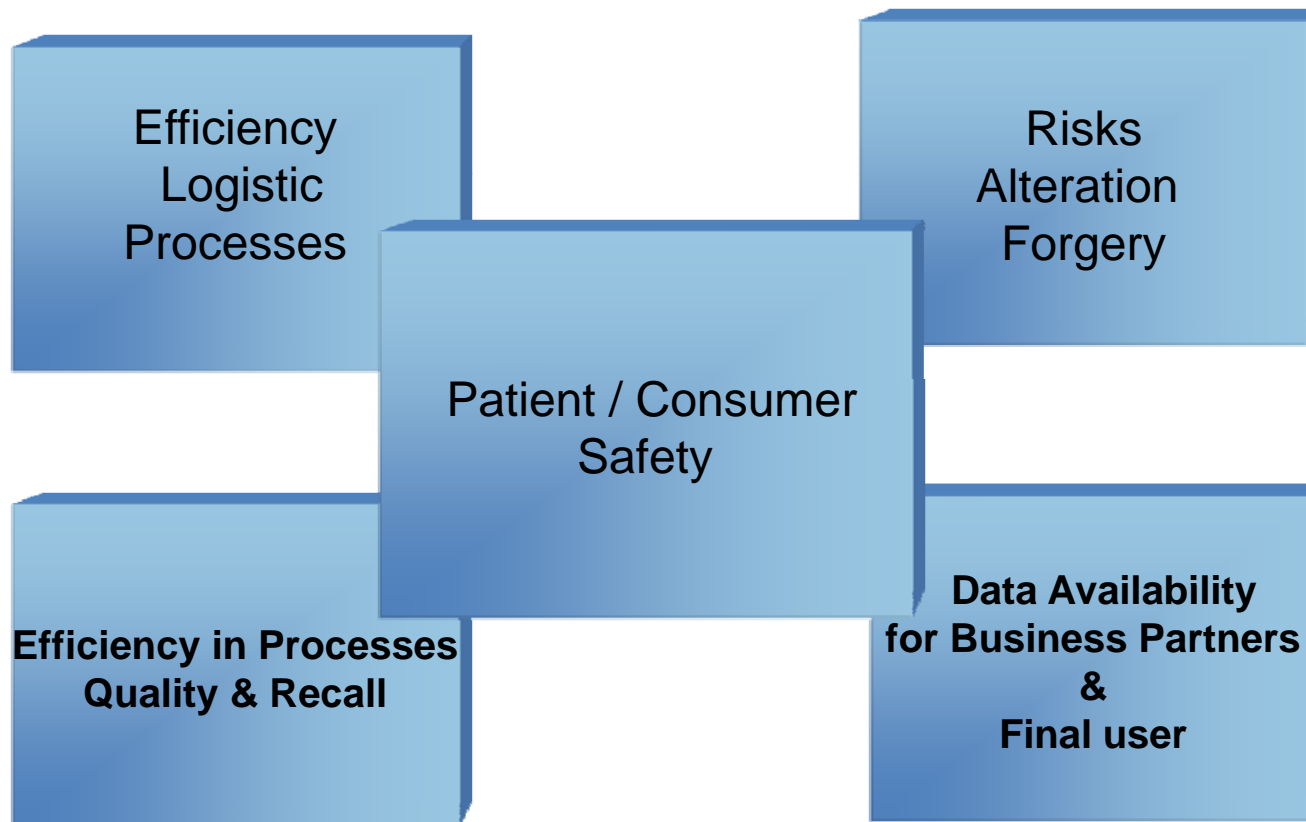
Objectives



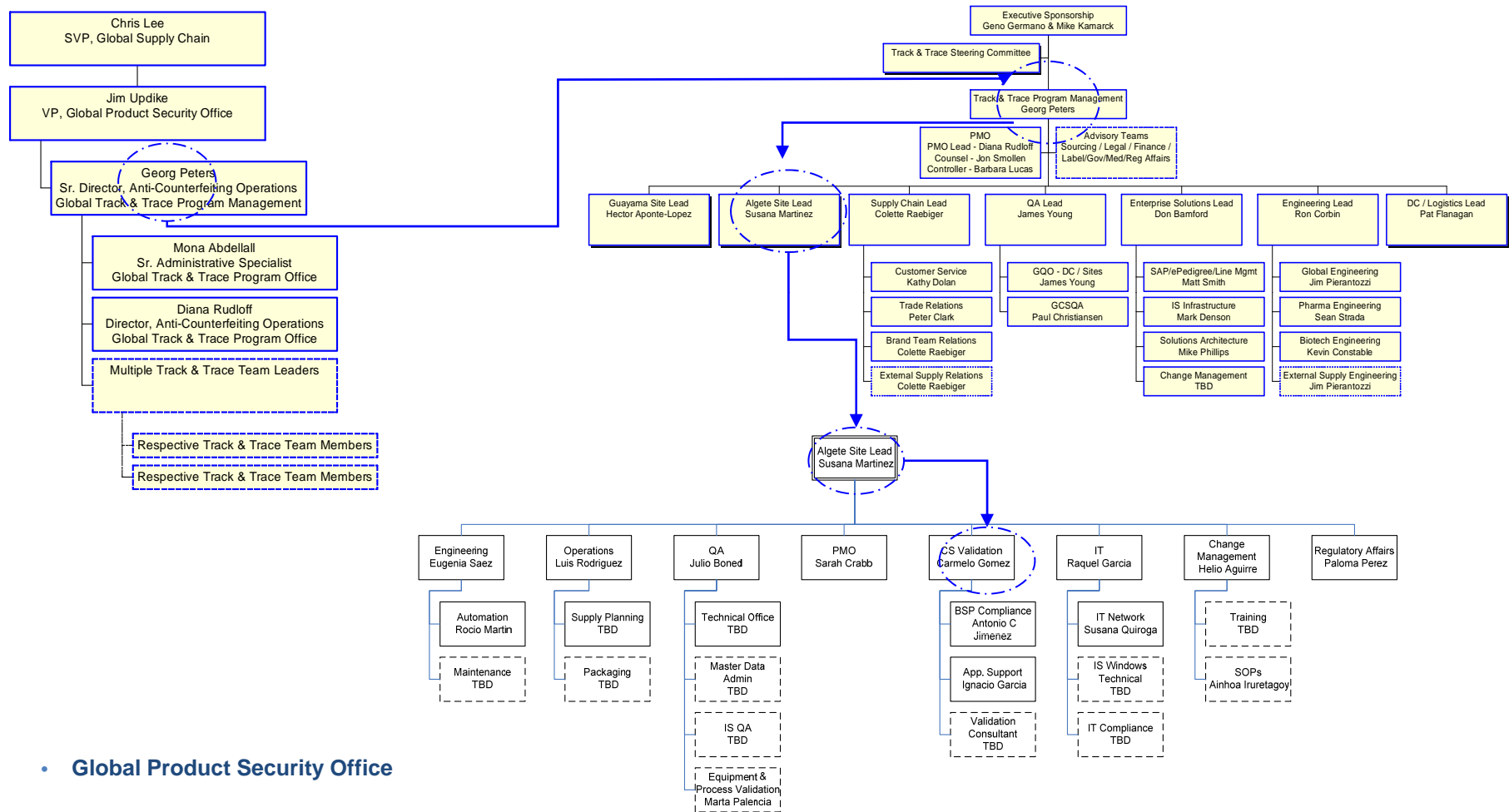
- Submit a proposal to improve to Improve **Follow up & authenticity** of Drugs in Colombia.
- Implement along the **value chain** a tracing method efficient & effective for Drugs ,medical and surgical materials based on standardized tools.
- **Guarantee Patient / Consumer Safety.**
- Contribute to the **competitiveness of participating organizations** as well as **information to final users.**
- **Provide information on pharmaceutical products to final consumers**
- Aline all the requirements to provide a domestic **solution under a global guideline based on a traceable and inter-operating system.**
- **Establish a common agreement for the implementation with all the actors involved in the value chain such as government and academic entities in the country.**



Compliance

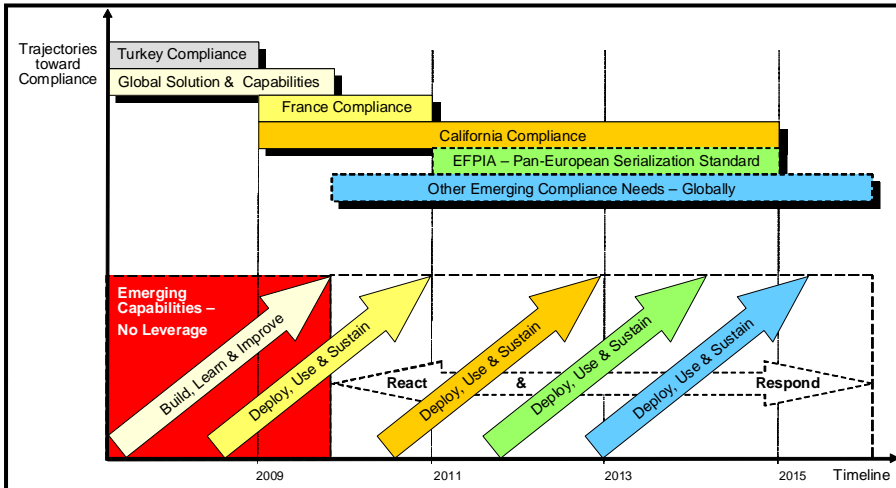


Wyeth Track & Trace Program Organization

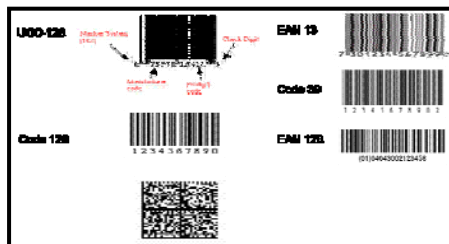
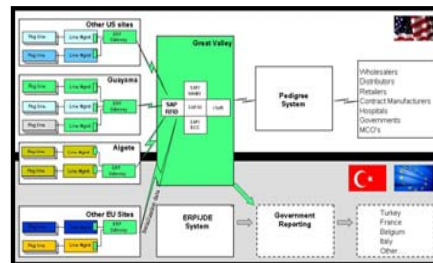
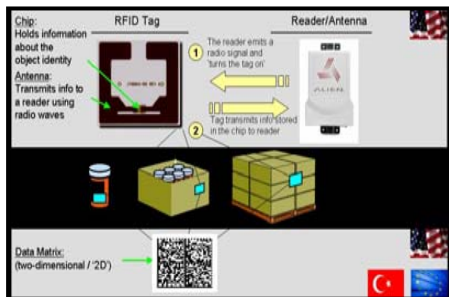


- Global Product Security Office
- Global Product Security Program

Wyeth Track & Trace Program Organization

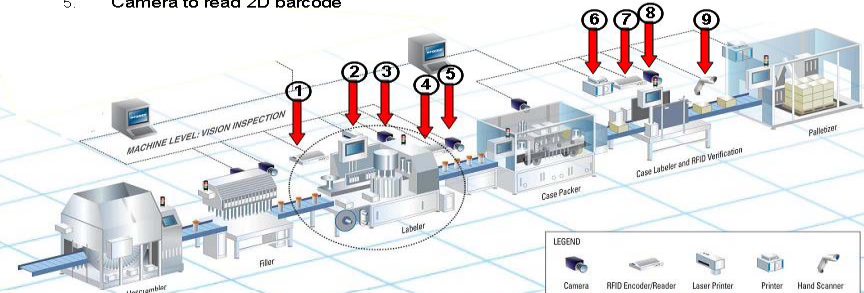


Key Compliance Requirements	Key Markets / Laws					
	California	Italy	Belgium	France	Turkey	EFPIA Standard
Coding						
Market Authorization Number	✓	✓	✓	✓	✓	✓
Lot Number	⊗	⊗	⊗	✓	✓	✓
Expiry Date	⊗	⊗	⊗	✓	✓	✓
2D Data Matrix	✓	⊗	⊗	✓	✓	✓
Serialization						
Unique Serial Number	✓	✓	✓	⊗	✓	✓
RFID Tag (Implicit)	✓	⊗	⊗	⊗	⊗	⊗
Item/Case Aggregation	✓	⊗	✓	⊗	✓ (Future)	⊗
Reporting						
ePedigree	✓	⊗	⊗	⊗	⊗	⊗
Point-of-Sale Authentication	⊗	⊗	✓	⊗	⊗	✓
Direct-to-MoH Reporting	⊗	✓ (Website)	✓	⊗	✓ (Future)	⊗
Data Management						
Market Authorization Number	MoH	MoH	MoH	MoH	MoH	MoH
Unique Serial Number	Manufacturer	MoH	MoH	-	Manufacturer	Manufacturer
Database Control	Supply Chain	MoH	MoH	Manufacturer	MoH	TBD

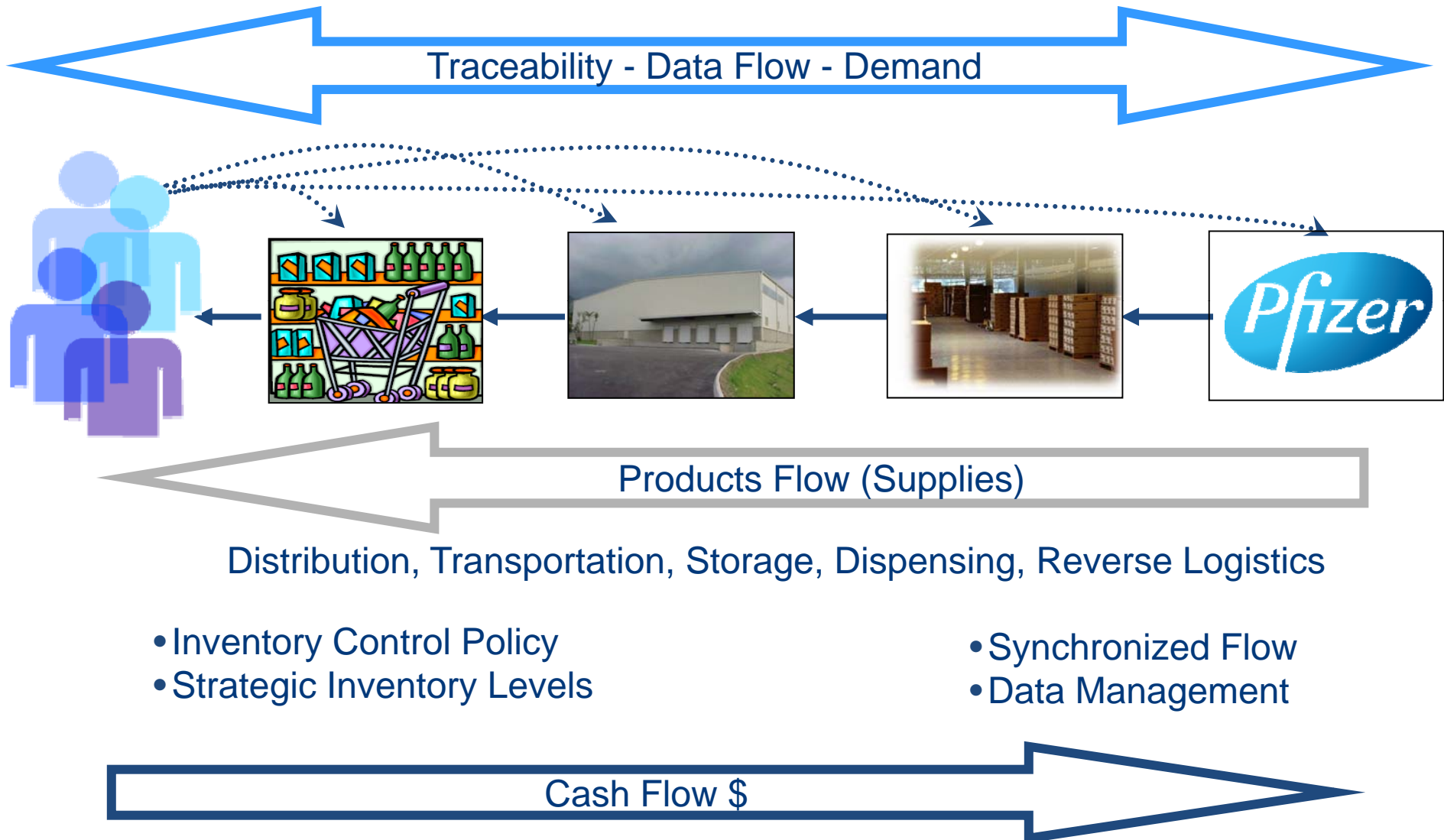


Bottle Packaging Line – RFID / 2D Data Matrix

1. RFID Writer (optional)
2. 2D Barcode Printer
3. Camera to verify 2D Barcode
4. RFID Reader (optional)
5. Camera to read 2D barcode
6. 2D Barcode Printer
7. RFID Reader / Writer (optional)
8. Camera to verify 2D Barcode
9. Handheld Reader (exceptions)



Background Process Flow



Implementation of a Traceable Model Based on an standard Technology

ALMACENES

EXITO

Pfizer

CABASnet

STL /
Sistema de trazabilidad en línea

CAFAM

Phases of The Pilot Program

Phase I



- Traceability Using Bar Codes Without Serialization
 - Sale Unit Levels through CABASnetSTL



- Work Groups Definition

Pharmaceutical Companies



(Pfizer Consumer Healthcare Today)

Distributors



Customers



ALMACENES

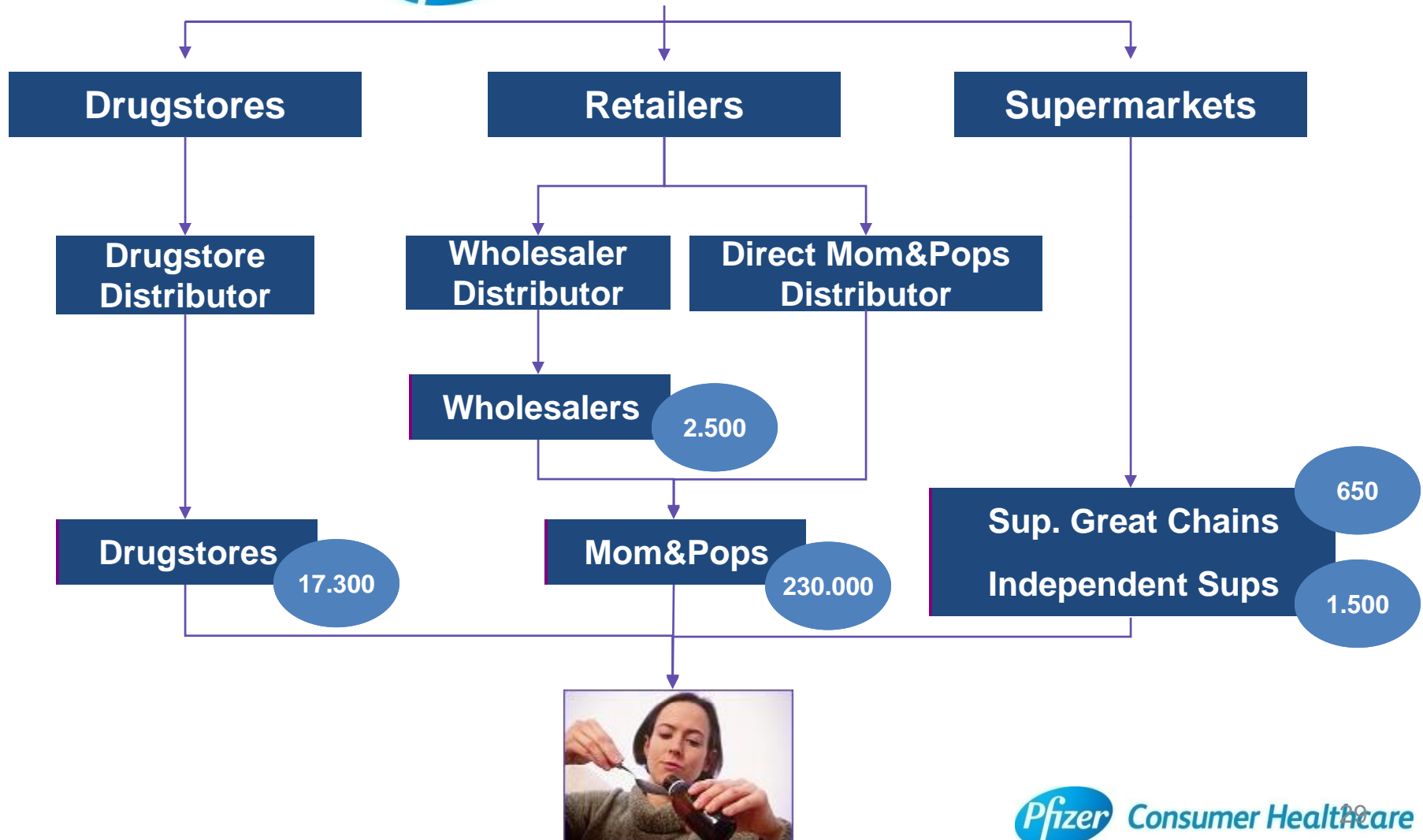


Phases of The Pilot

Commercial Universe Colombia



Pfizer Consumer Healthcare



Phases of The Pilot

Commercial Universe Colombia



GGG

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Phases of The Pilot

Commercial Universe Colombia



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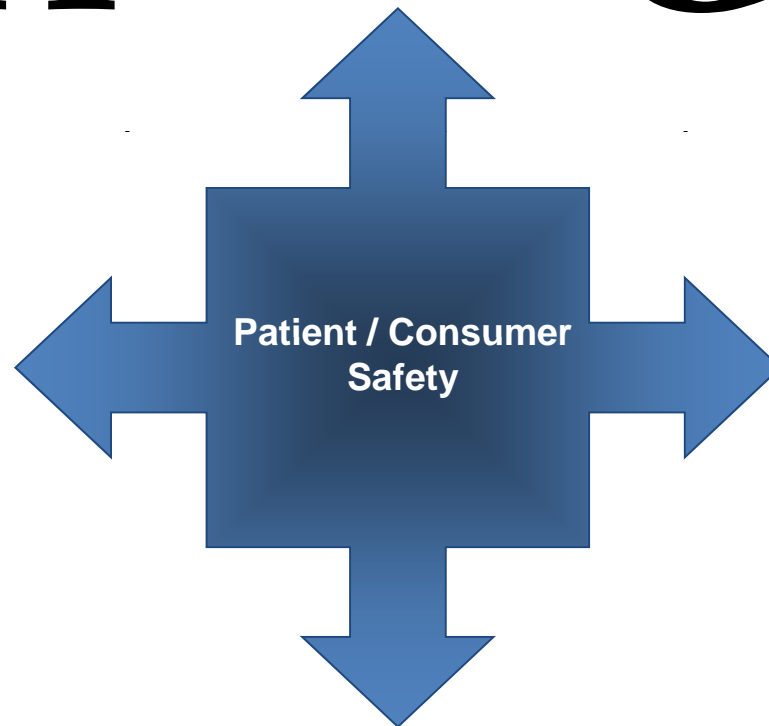
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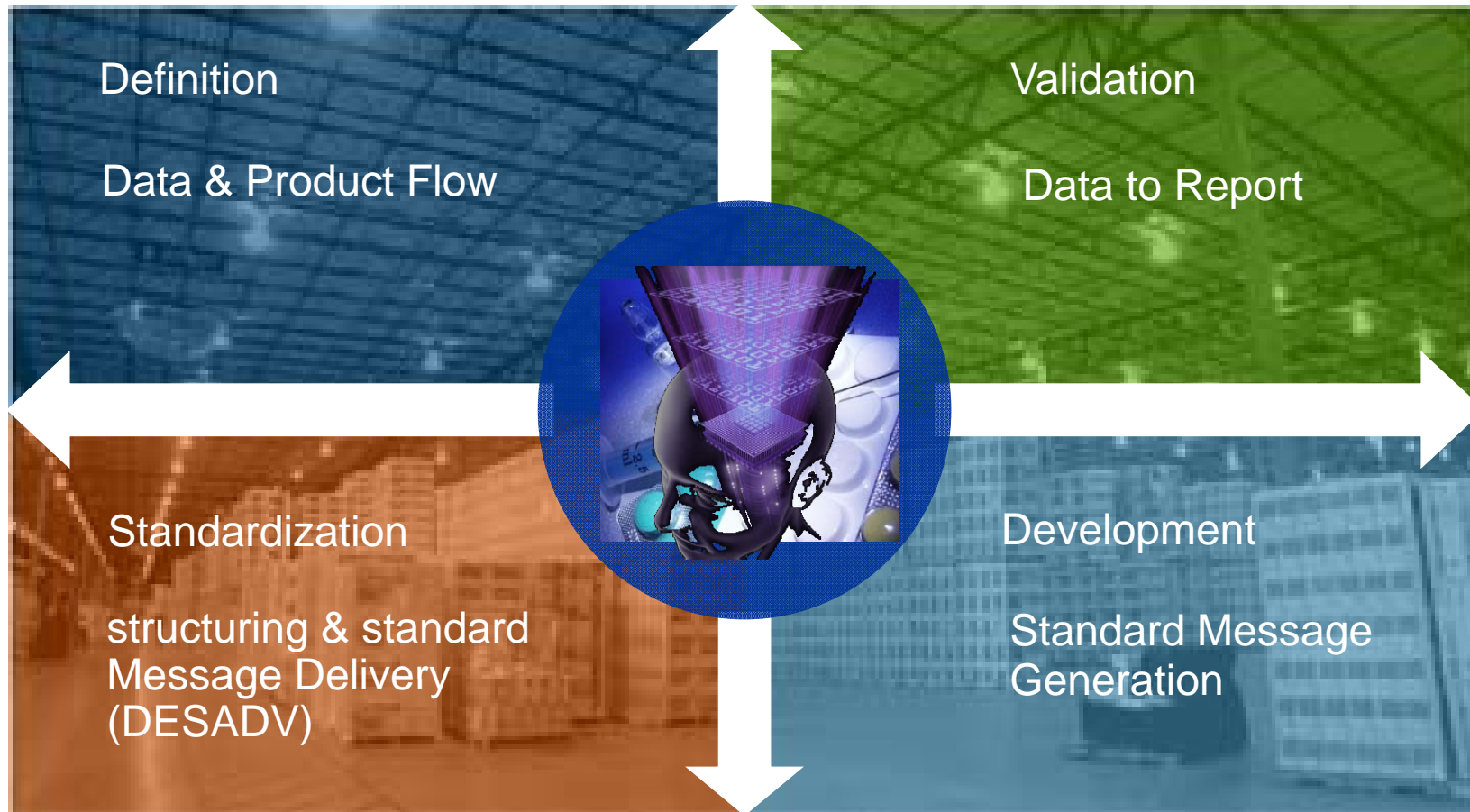
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Phases of The Pilot

Walk Through Requirements & Process analysis



Phases of The Pilot

Removal, Requirements and Process Analysis.



STRATEGIC PARTNERSHIP PROCESS

Definition of the network of value (product flow and flow information)

State CABASnet Synchronization report and review of electronic standar

Definition of product portfolio susceptible to GTIN

Definition of Locations GLN

Definition of messages and Media DESAV

Placement Process Information and Consultation in CABASnet STL

Timing of Placement Information in STL Production

PROVIDER

CONSUMER



AVISO DE DESPACHO		WYETH CONSUMER HEALTHCARE	
CLIENTE		ALMACENES ÉRITO S.A	
PTO ENTREGA		CEDI LAS VEGAS	
PTO. VENTA		LLE Y MARACAIBO	
508		77010011060806	
No. O.C.	02008777	Nº CAJAS	24
No. FAC.TURA	2173101	No. ECTIBA	1 DE 2
FECHA DEL ENVÍO : 01/06/2008			
00377020060002080000			



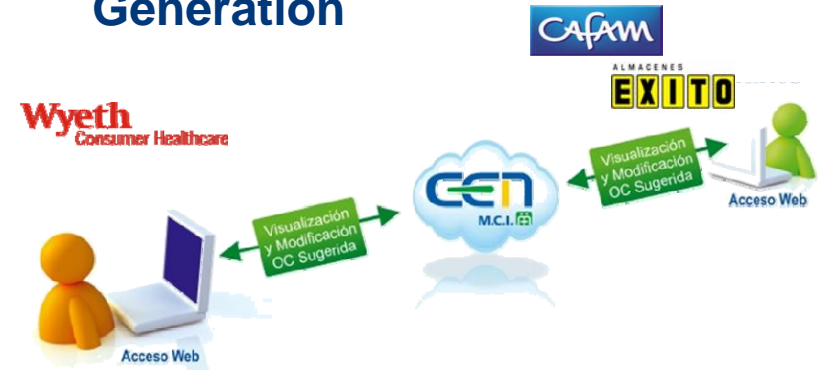
SSCC: Serial Shipping Container Code

Phases of The Pilot Electronic Cycles

- 1st Cycle – Catalog Synchronization
PRICAT



- 2nd Cycle – Purchase Order Generation



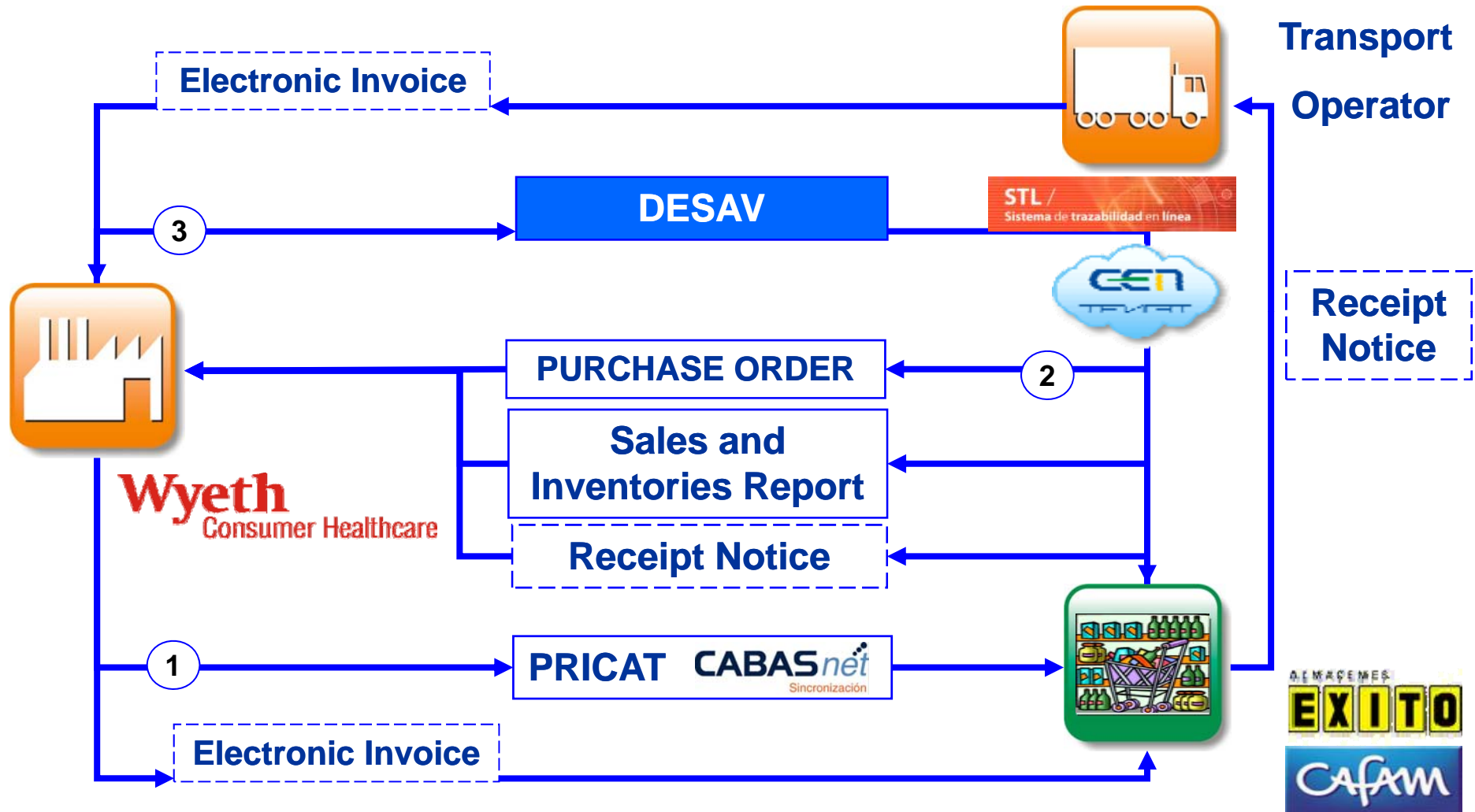
- 3rd Cycle – Shipping Notice Generation
DESAV



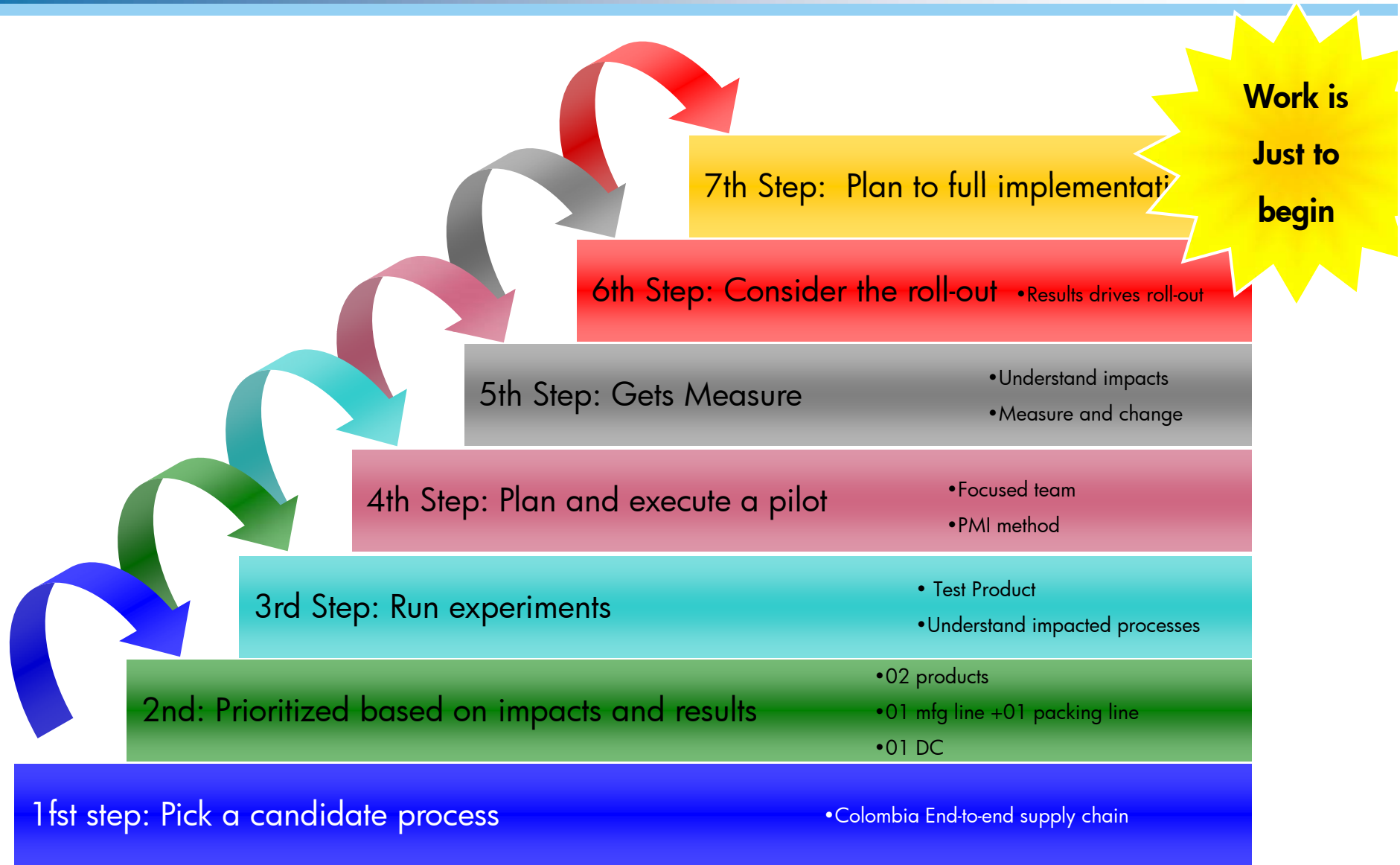
- 4th Cycle – Shipping Notice



Phases of The Pilot Electronic Cycles



Phases of The Pilot Implementation Steps



Lessons Learned



- **Standard Report**

- ▶ **Leadership Support**

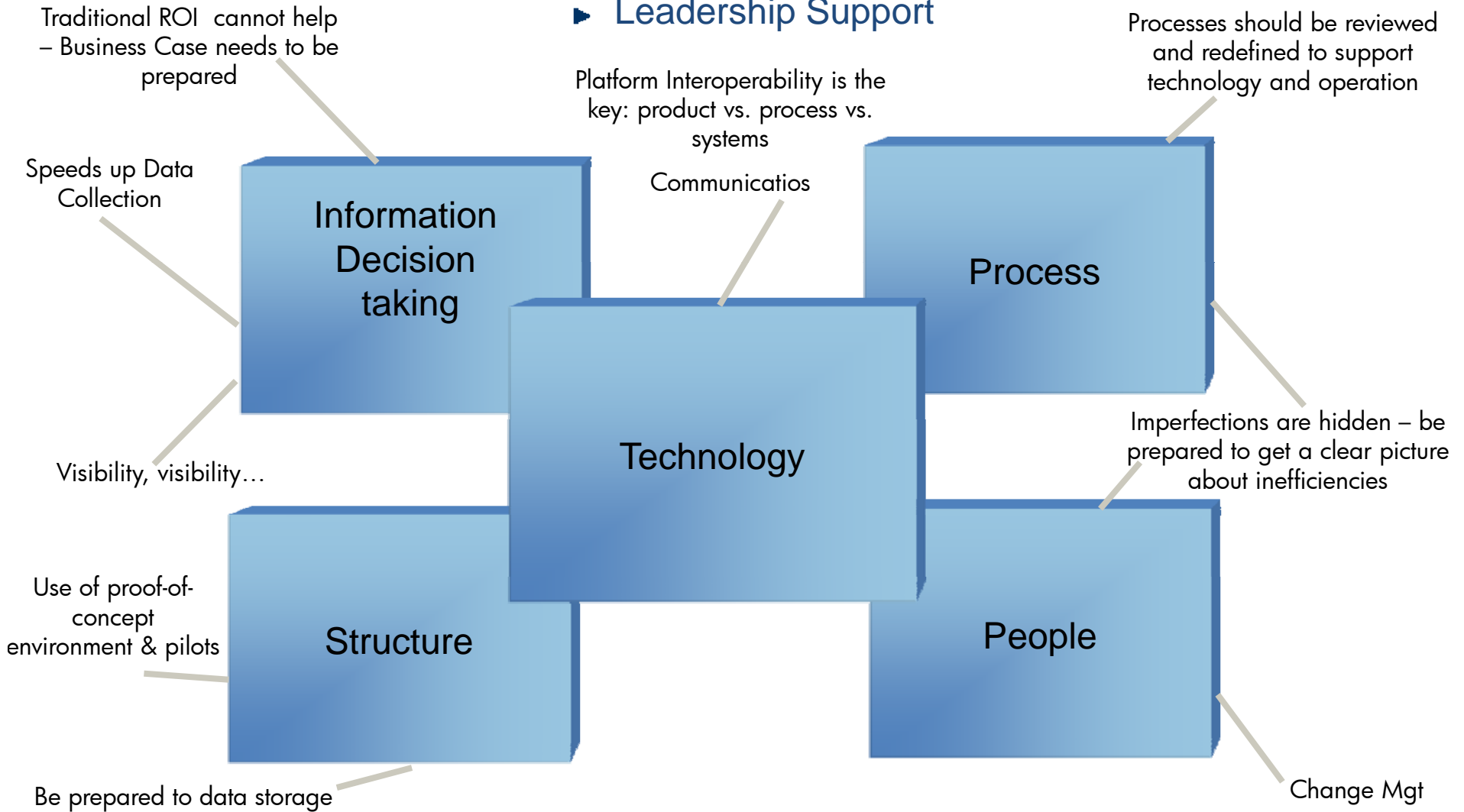
Platform Interoperability is the key: product vs. process vs. systems

Communications

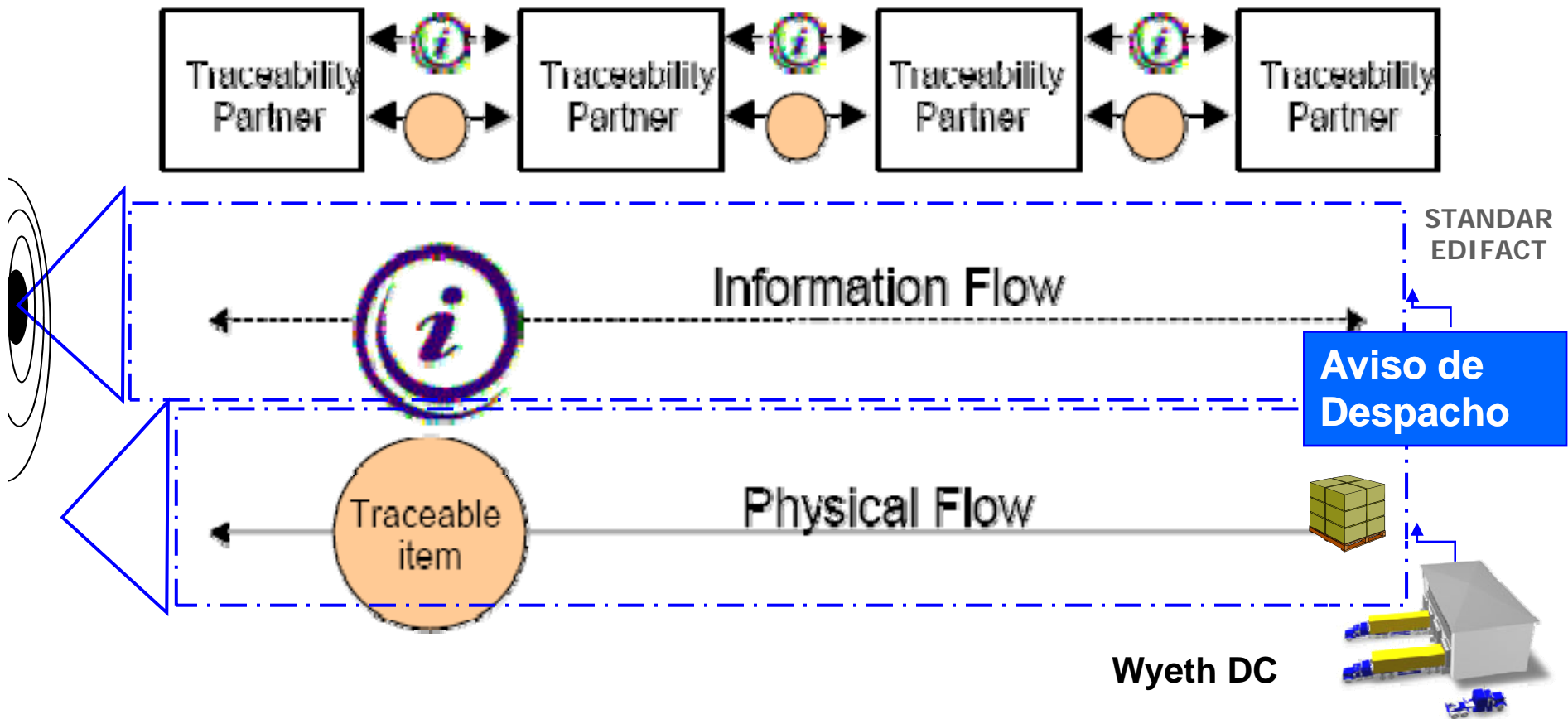
Processes should be reviewed and redefined to support technology and operation

Imperfections are hidden – be prepared to get a clear picture about inefficiencies

Change Mgt



Conclusions



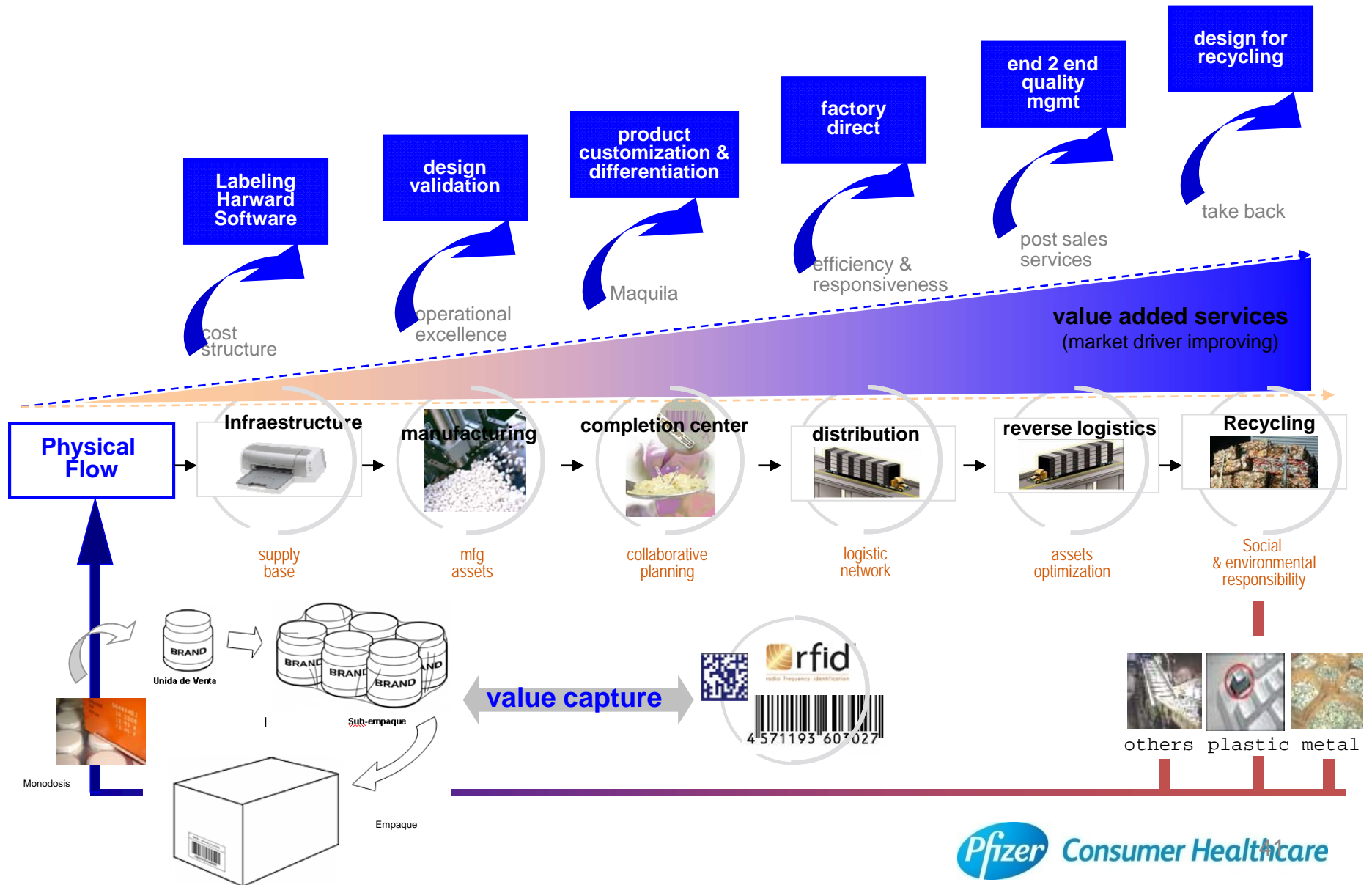
- Establish the importance of **process Flow Separation: Information Flow vs Physical Flow**, on Phase I : Only **Information Flow** policies and processes should be regulated.

- **Electronic Data Exchange based on an Standard Report.**
- Create an implementation of **Despatch Advice XML Format**, for the Global access of the tool.
- **Parameter Definition**, range & Product characteristics that triggers processes by Phases of implementation: 1, 2, 3, 4...
- Define Inventory System Control for the Pharmaceutical category. **FEFO**, analysis, impacts, ...
- A common and synchronized effort is needed as a result of the performance of all and each one of the actors in the **Value Chain** including Time, Resources and technological developments as well as an structured work plan.

Conclusions

- An Information Repository of the category like **CABASnet STL** is needed. One of the Problems identified today to do a trace is that there is no Information Flow that guarantees access to the drug tracing in Real Time . Lack of Complex Systems Infrastructure for the storage and management of the information.
- Accomplishment of a better control of the Drug **Distribution Chain** adopting new ways to make easier the identification of forged products and loss prevention as well as better ways to trace the product.
- Grant access to the information contained in a data base. Assign a unique ID for each product during the manufacturing process.
- The Drug Tracing System should be able of Capturing, Store, Process and Transmit information regarding production, circulation and commercialization of drugs

The next generation supply chain



GRACIAS
THANKS
OBRIGADO
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