



Traceability in Healthcare: what does it mean?

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Healthcare Traceability... our agenda

- Some key principles about Traceability
- Traceability, authentication and pedigree
- Trends illustrated by examples
- Questions

SOME KEY PRINCIPLES ABOUT TRACEABILITY

GS1 Healthcare Some key principles...

Security, traceability and efficiency in Healthcare currently at the forefront of government regulations and industry concerns around the world



Numerous, and often irreconcilable solutions are being (or have already been) proposed **adding cost and complexity** for all stakeholders



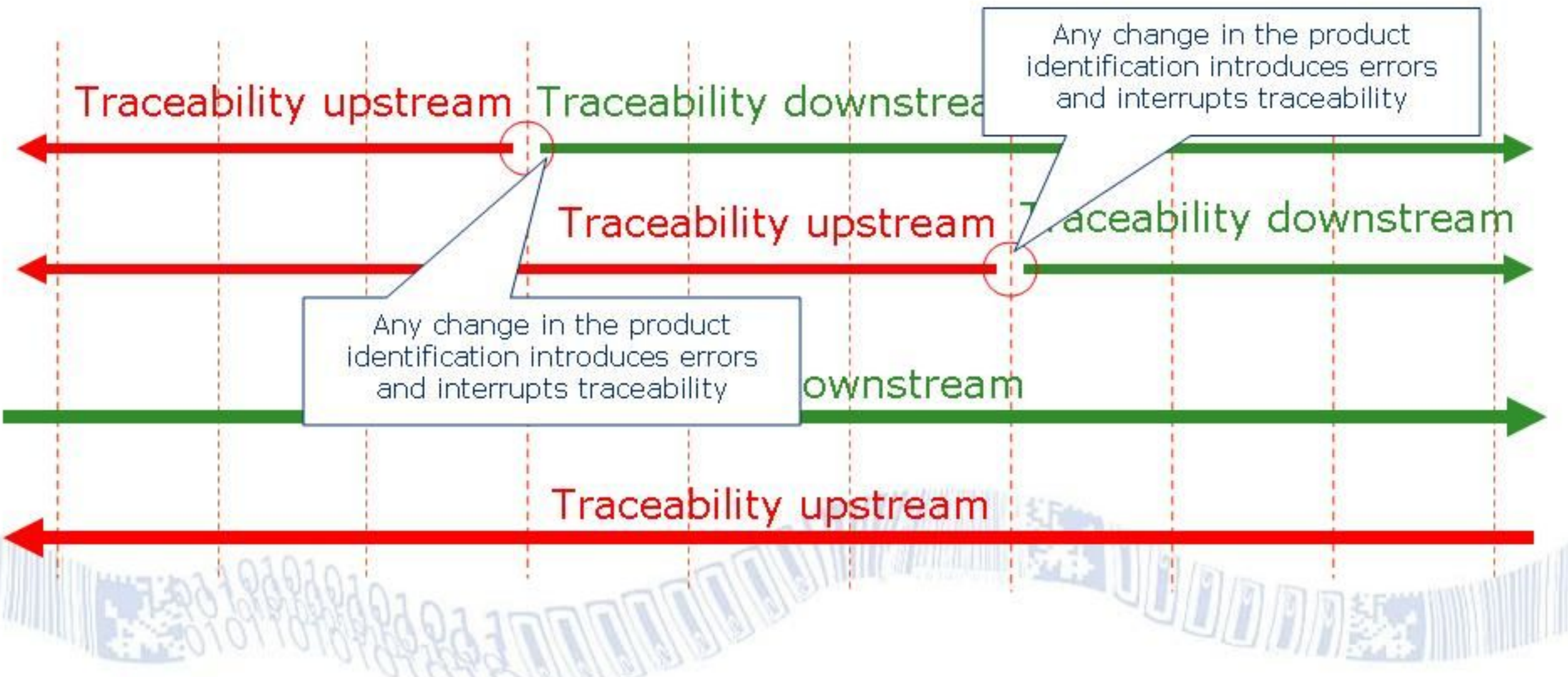
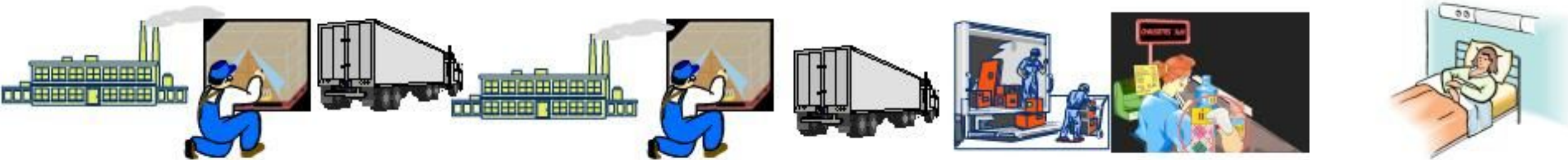
Healthcare Traceability is effective with...



... international standards ?



Traceability is a shared process



...standardised identification keys...

**Provide access to information held in computer files –
Information about company/location, package,
product, price, etc.**





Healthcare

... a shared process requiring...

Automatic Identification & Data Capture (AIDC)
efficient and accurate

Data carrier



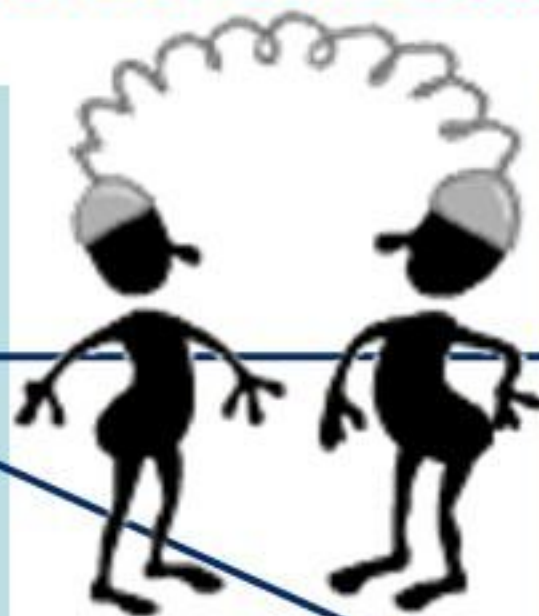
Linear bar code



2-D bar code



RFID tag



Scanner / Reader



Laser scanner



Camera-based scanner



RFID Reader

TRACEABILITY, AUTHENTICATION AND PEDIGREE



GS1 Healthcare Traceability

Traceability is **the ability**...

to track forward the movement through specified stage(s) of the extended supply chain and...

to trace backward the history, application or location of that which is under consideration



Healthcare How does traceability work?

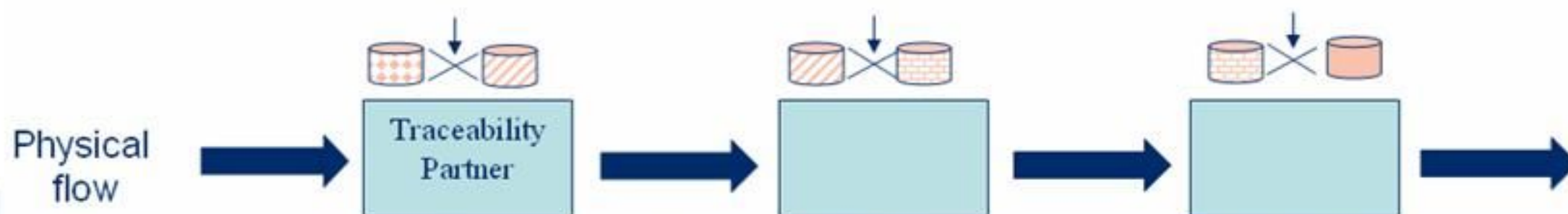
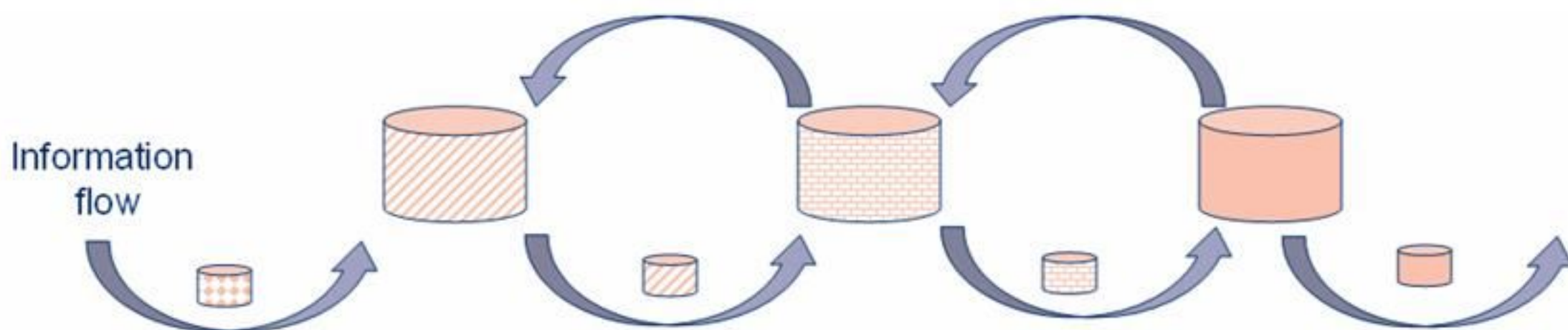
The GS1 Global Traceability Standards provide guidance on how to implement effective traceability solutions

- **Unique identification**
 - Global product identification number
 - Lot/batch number or serial number (unique number at the unit level)
- **Data capture**
 - Bar coding or radio frequency identification (RFID)
- **Links management**
 - Managing identification from the point-of-manufacture to the point-of-sale/point-of-care
- **Data communication**
 - Associate the physical flow of products with the information flow
 - Different information sharing models

GS1 Healthcare Information sharing model 1

One up, one down

- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor

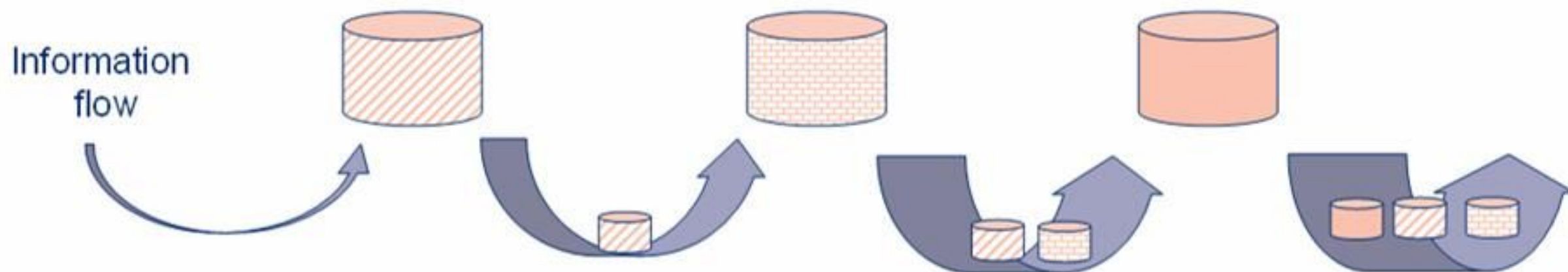




Healthcare Information sharing model 2

Cumulative Tracking (e.g., California ePedigree)

Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.



Physical flow

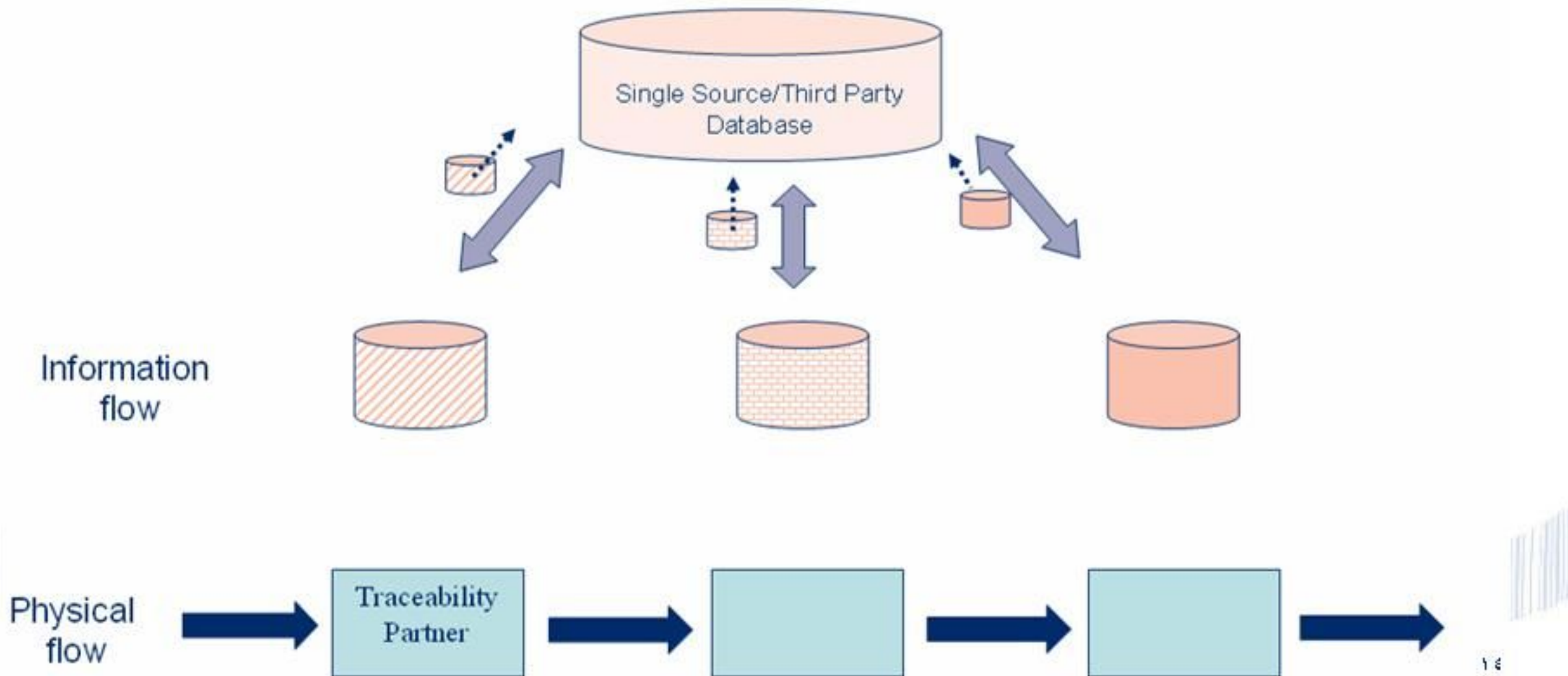




Healthcare Information sharing model 3

Single Source Database

The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a Third Party.

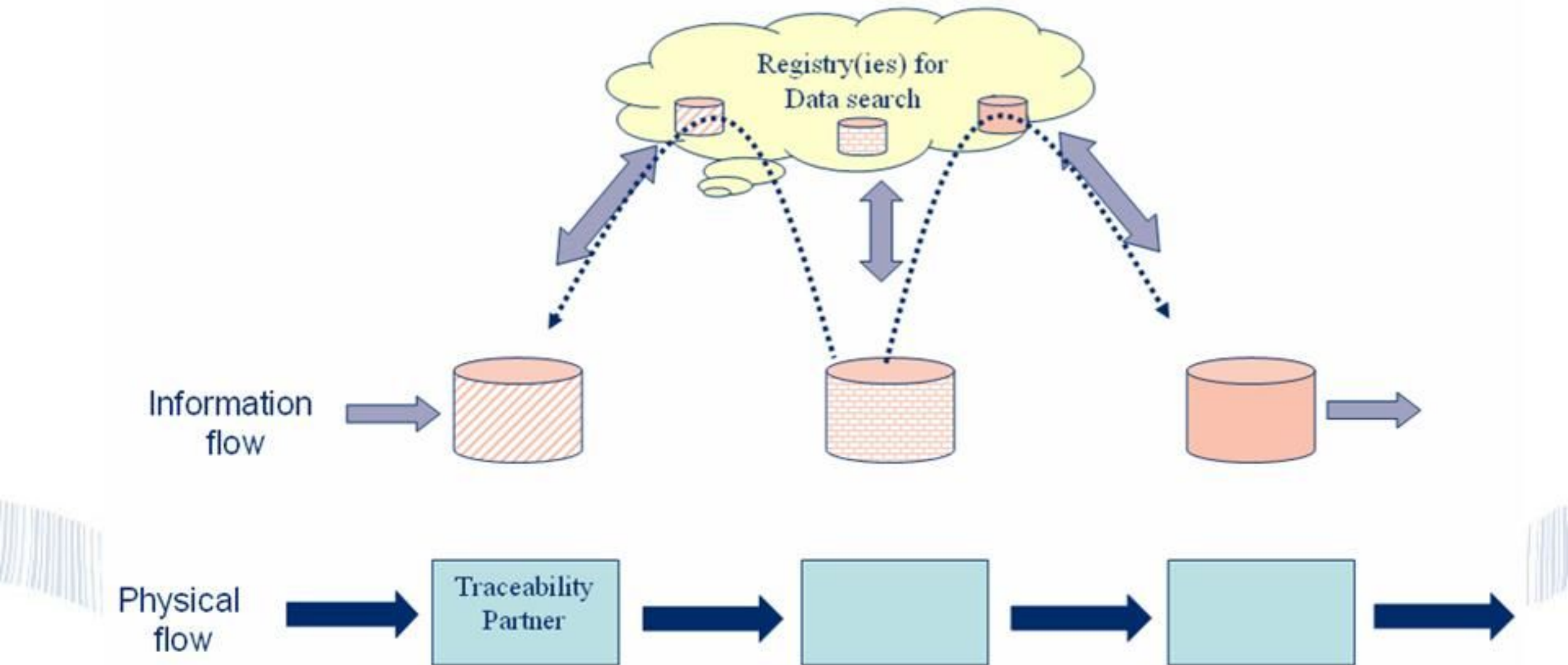




Healthcare Information sharing model 4

Distribution Information Sources

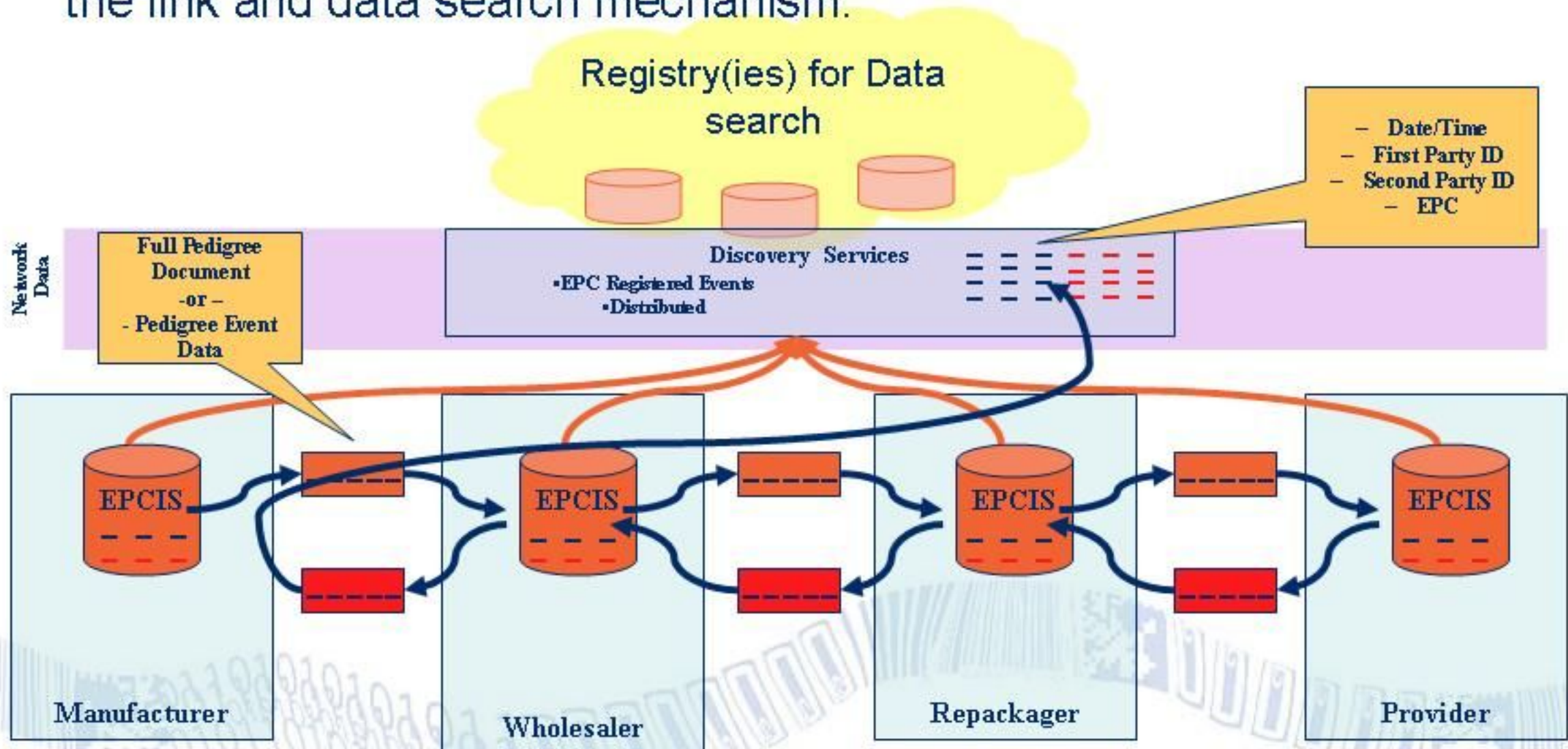
Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism.



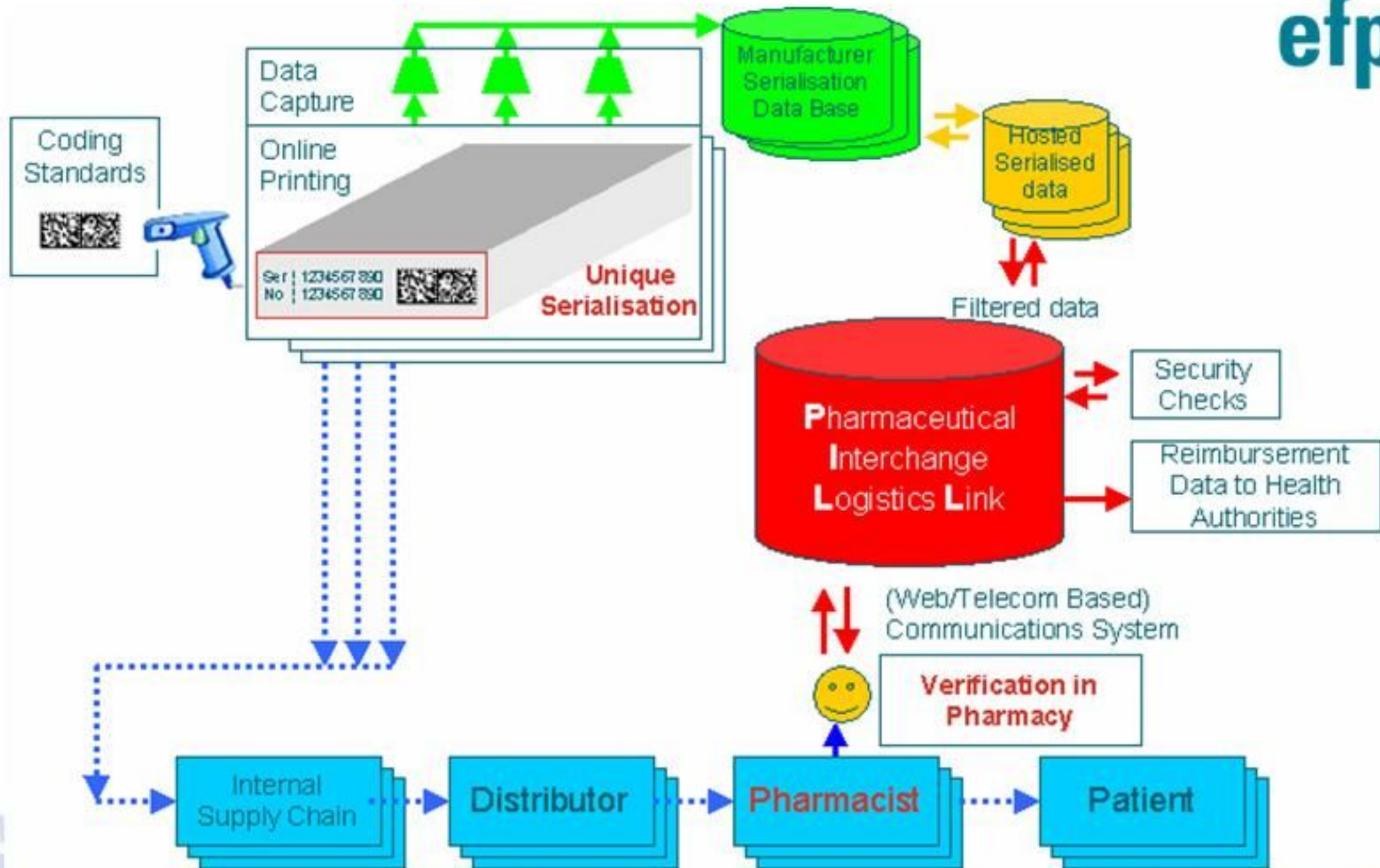


Distribution Information Sources

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TRENDS ILLUSTRATED BY EXAMPLES





Anti-Counterfeiting Strategies

Multiple actors / multifocal threat

Multi-level (“holistic”) strategy

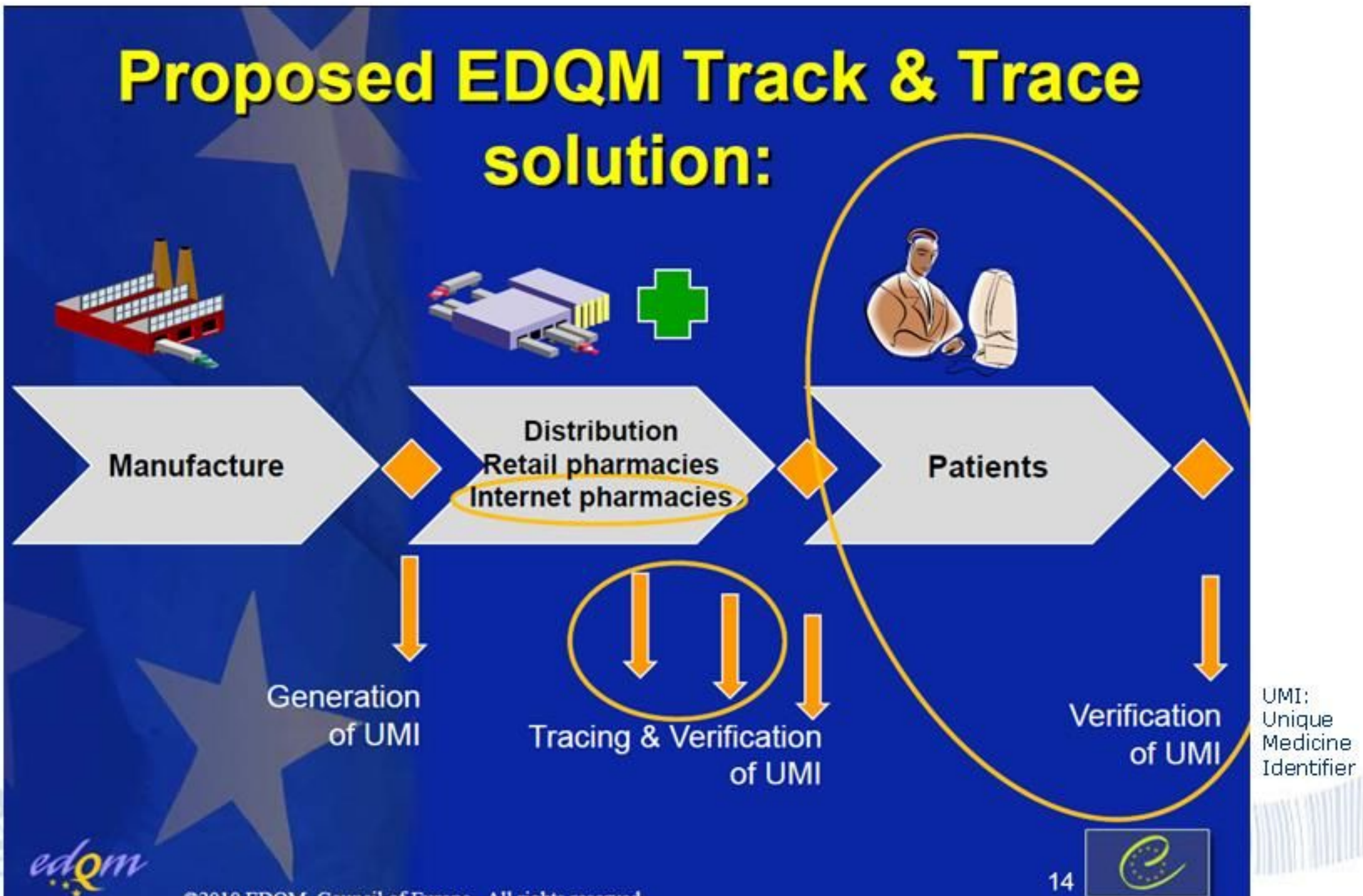
- Custom level (importation)
- Legal instruments (pharmaceutical crime)
- Pharmaceutical level
 - Inspection
 - Packaging (traceability of serialised items)
 - Testing (detection / provide enforcement officers with evidence)
 - Surveillance of pharmacovigilance reports from users





Healthcare Example: CoE blue print

Proposed EDQM Track & Trace solution:





ITS Database

Data Flow

Product Flow

E-Pedigree

Consumption

Manufacturer /
Importer

Distributor

Pharmacy

QUESTIONS ?

Contact



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