Big Data and Serialization for Supply Chain Value Creation

Examples from the healthcare industry

6th European Conference on ICT for Transport Logistics (ECITL), Zaragoza Spain

October 23-25, 2013

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Agenda

- Managing risk in globalizing supply chains
- Big Data in the pharma value chain
- 7 data flows - Serialization learnings from Biologics
    1) Physical movement of goods/aggregation
    2) Data about the goods
    3) Quality data
    4) Legal data (custody)
    5) Financial data
    6) Regulatory data
    7) Product Lifecycle Management
- Mobile/IT innovations – "Connecting the Dots"

Growth of FDA Regulated Imports
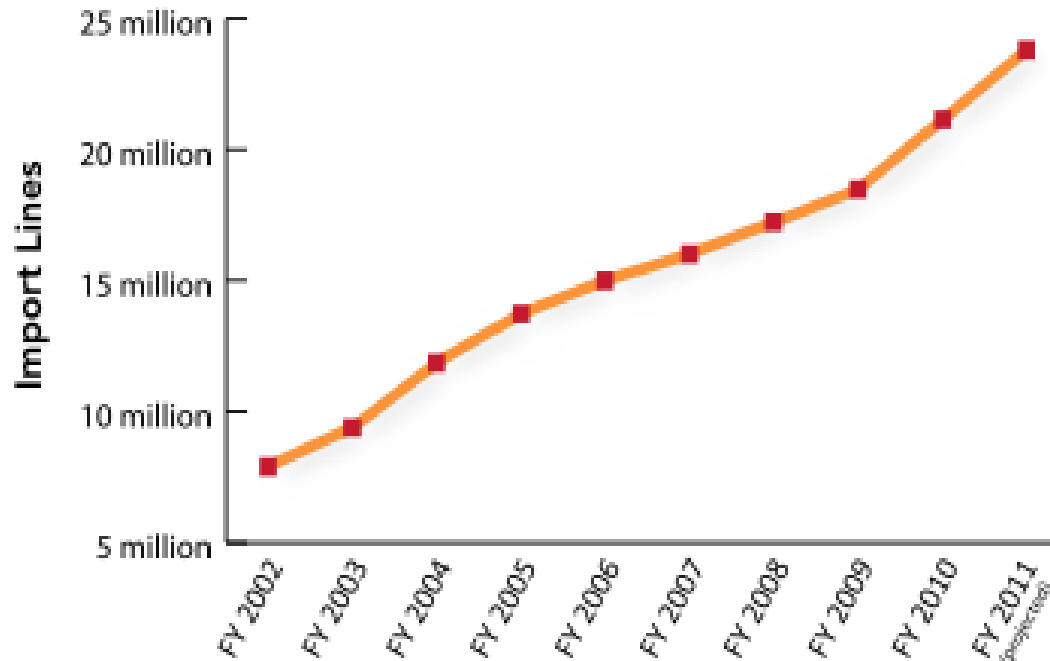
FY = U.S. Government fiscal year

NOTE: An import line represents the portion of a shipment listed as a separate item on an import entry document. Items must be listed separately if their tariff description differs from other items in the shipment.

Source: Veneziano, D. 2011. Import Stats FY 2002-2010. U.S. FDA, Division of Import Operations and Policy, Office of Regulatory Affairs, Washington, DC.

Big Data in Healthcare
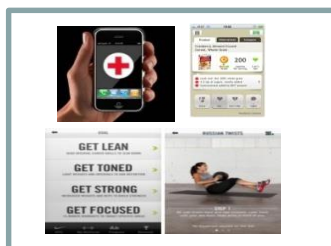
Center for Biomedical Innovation
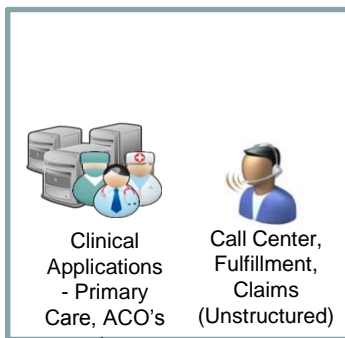
AUTO-ID LABS

Wireless Personal Health Devices & Sensors

Unstructured Data

Clinical Data Repository
Enterprise Data Warehouse
OLTP/OLAP

Reports

mHealth

Big Data Processing
and Integration

Analytics
Data Mining
Predictive Modeling

Clinical Applications - Primary Care, ACO's etc.

Call Center, Fulfillment, Claims (Unstructured)

NHIN   HISP

surescripts
Is Expanding its National Health
Information Network

HIEs

Clinical Systems (EHRs)

External Partners

Big Data Repository
(Cloud based Analytics)
ClickStream, Image, Text, Scientific, Medical, Pharmacy

Abhi Dhar, CTO, eCommerce, Walgreens
2012 Auto-ID Labs Big Data Conference

10/24/2013

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Smartphones impact operations

SCAN >40%

of online prescriptions from mobile

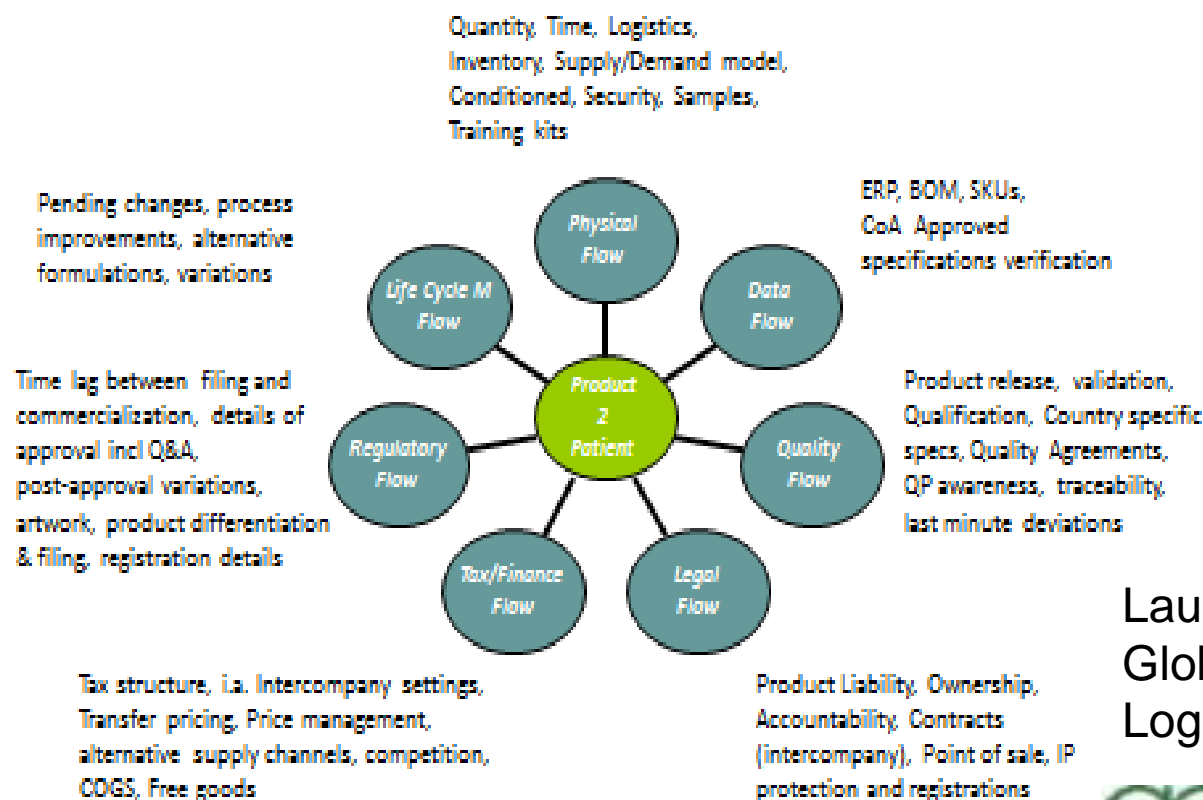2012 MIT Auto-ID Labs Big Data Conference
Abhi Dhar | CTO eCommerce

7 Flows

Alignment of flows is pivotal to ensure Success:
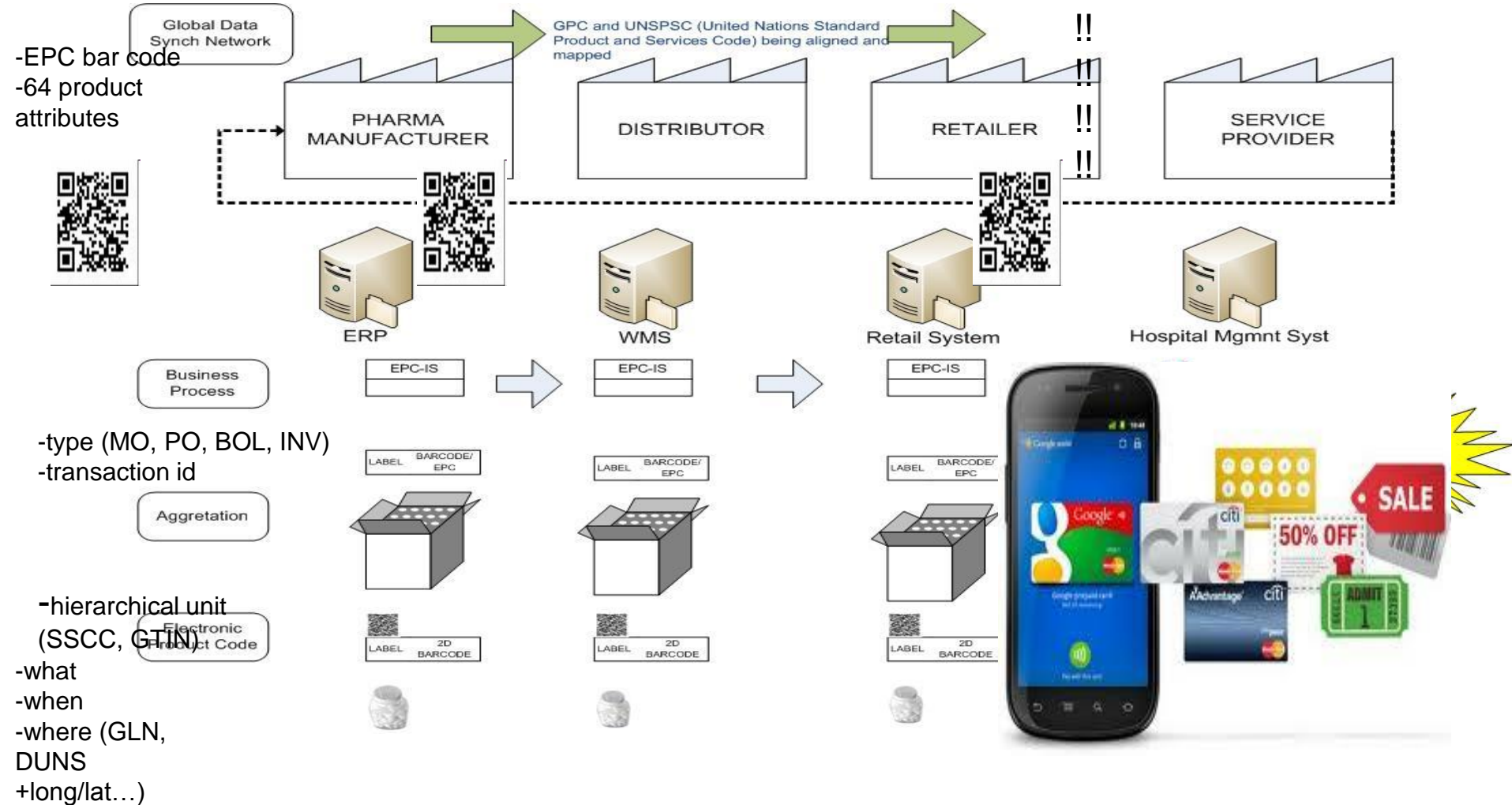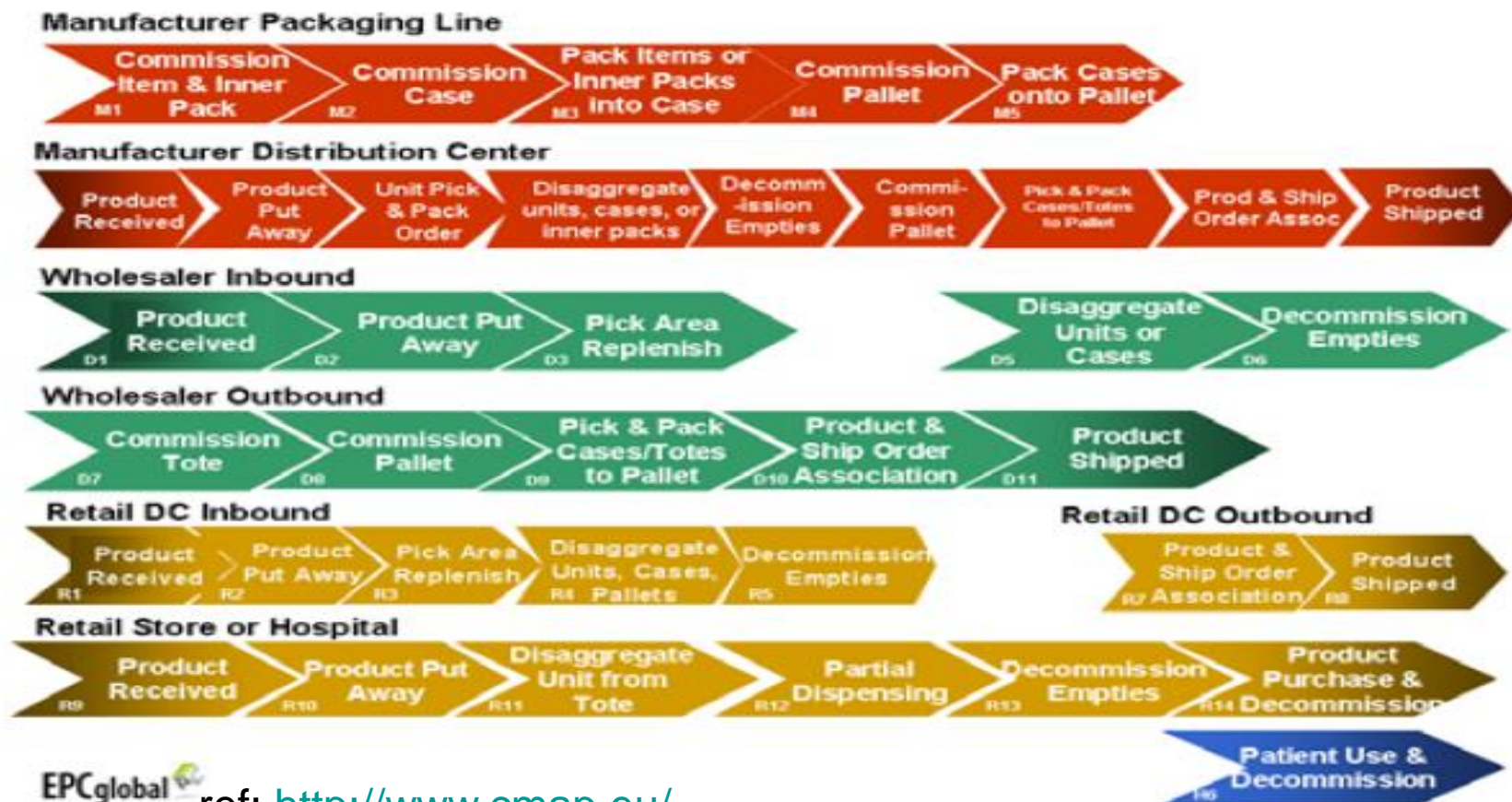Living up to the Expectation and Commitment

Quantity, Time, Logistics,
Inventory, Supply/Demand model,
Conditioned, Security, Samples,
Training kits

Pending changes, process
improvements, alternative
formulations, variations

ERP, BOM, SKUs,
CoA Approved
specifications verification

Physical Flow

Life Cycle M Flow

Data Flow

Time lag between filing and
commercialization, details of
approval incl Q&A,
post-approval variations,
artwork, product differentiation
& filing, registration details

Regulatory Flow

Product 2 Patient

Quality Flow

Product release, validation,
Qualification, Country specific
specs, Quality Agreements,
QP awareness, traceability,
last minute deviations

Tax/Finance Flow

Legal Flow

Tax structure, i.a. Intercompany settings,
Transfer pricing, Price management,
alternative supply channels, competition,
CDGS, Free goods

Product Liability, Ownership,
Accountability, Contracts
(intercompany), Point of sale, IP
protection and registrations

Laurent Boer, VP
Global Distribution &
Logistics

genzyme
A SANOFI COMPANY

1. Physical Flow of Supply Events

-EPC bar code
-64 product attributes

-type (MO, PO, BOL, INV)
-transaction id

-hierarchical unit (SSCC, GTIN)
-what
-when
-where (GLN, DUNS +long/lat…)

2. Data Flows in Processes

Manufacturer Packaging Line

Manufacturer Distribution Center

Wholesaler Inbound

Wholesaler Outbound

Retail DC Inbound

Retail DC Outbound

Retail Store or Hospital

ref: http://www.cmap.eu/
cMap Project will define the correspondences between CPV, eCl@ss, GPC and UNSPSC and mappings

3. Quality Flows - GMP and QbD

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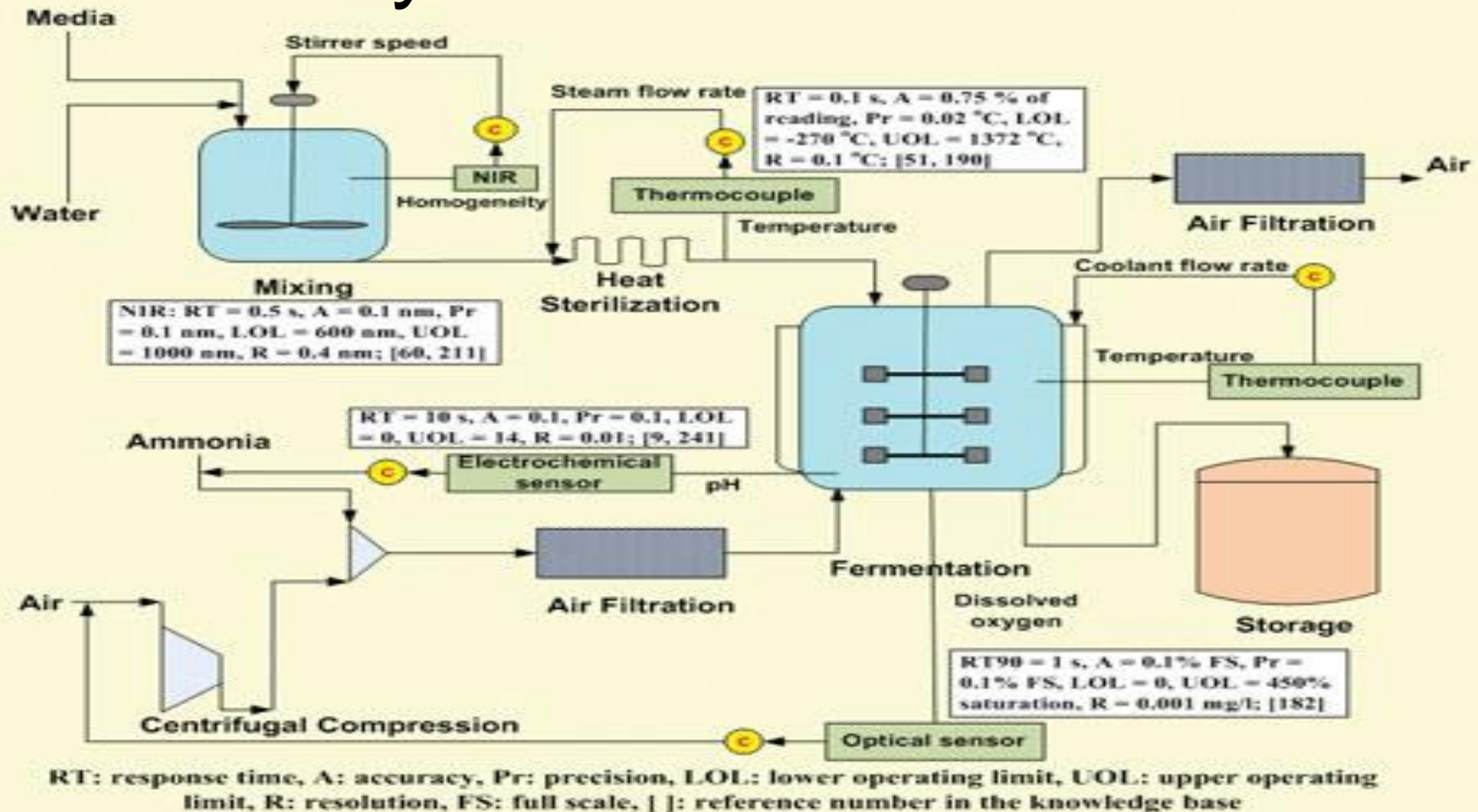
4. Legal Flows - Common Risk Analysis

Improving Security through Visibility

5. Finance Flows - Who owns the data?

- Market disruptors

  – Outsourced Excipients, API's

  – Recombinant proteins, vaccines, and antibodies 50% of revenue top 100 drugs

  – Disintermediating supply chain

    • Cell based therapies are direct to clinic

  – Medical device consumables enabled by RFID;

    • 20% of hospital purchases

6. Regulatory Flows – FDA Roadmap

Develop the Knowledge Architecture and Infrastructure
that enables smooth FDA operations, efficient review processes,
risk-based analytics, and secure and seamless collaboration with
public and private partners

FDA Information Management and Office of Information
Management Strategic Plan Version 1.1
FY2012 - FY2016 - Eric Perakslis, CIO & Mike Coene, CTO

7. PLM Data made up of lots Little Data

Semantic
Mark-up
"Rich Snippets"

GENES
Contain recipes
for protein

PROTEIN
MACHINE

DNA

Information is
stored in genes
and other DNA
sequences

PROTEINS

Proteins act alone
or in complexes
to perform all
cellular functions
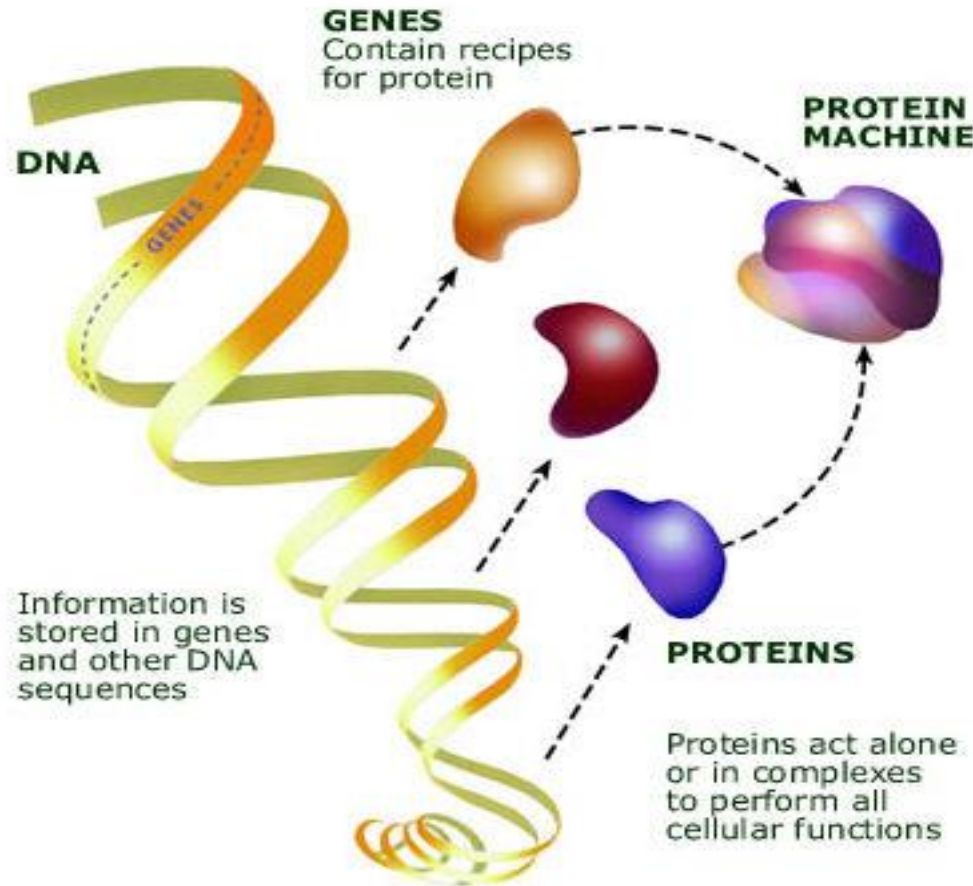
Linking Physical to Information Flows
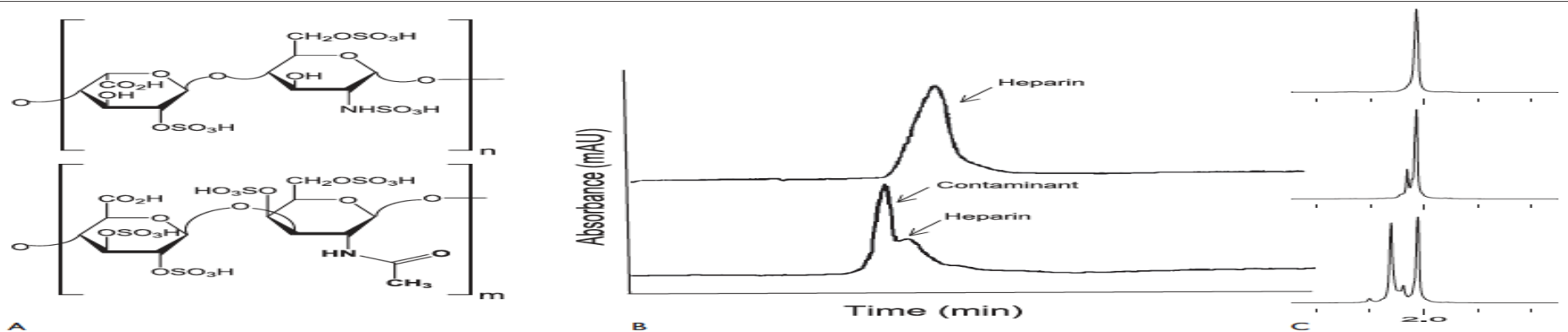
Detection of a contaminant within heparin.

A) Structure of heparin (*top) and OSCS (bottom) shown in acidic form.*

B) B) Representative CE results for a clean heparin sample (*top) and a contaminated heparin sample containing OSCS (bottom)*
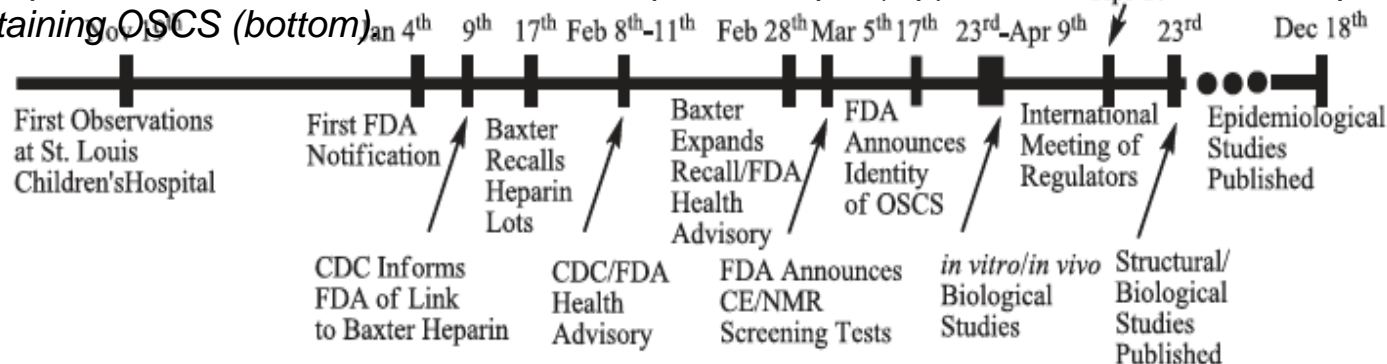
"From crisis to opportunity: A perspective on the heparin crisis;"
Ram Sasisekharan1; Zachary Shriver2

Barcode Med Admin

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Monitoring the Interaction
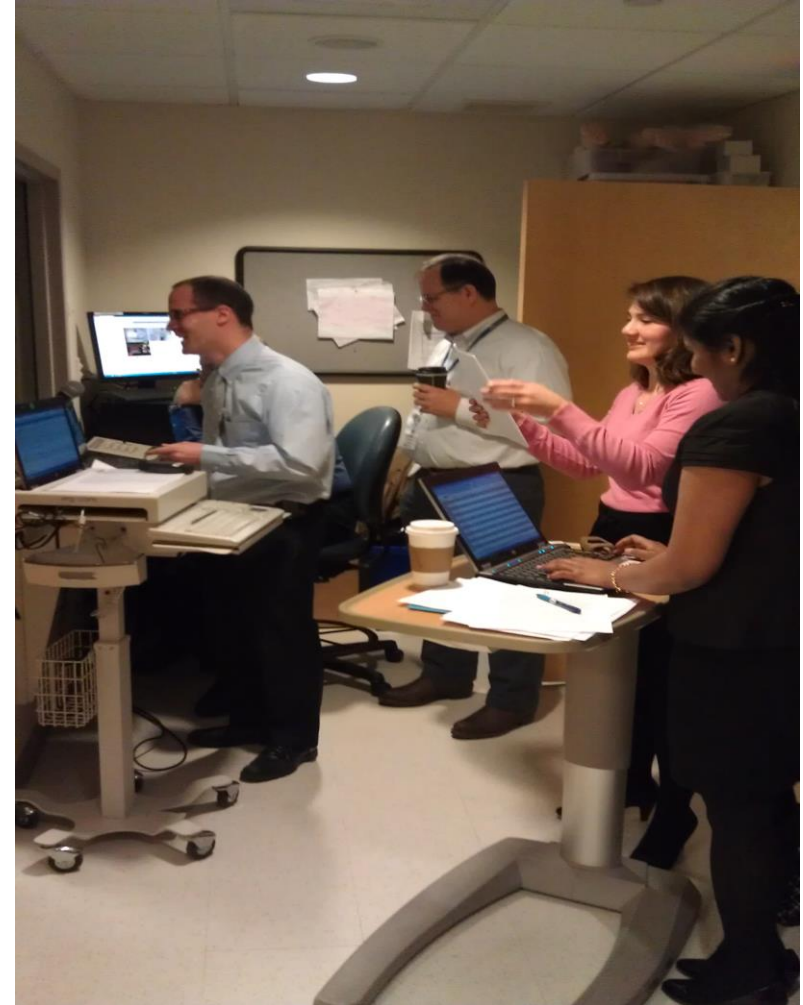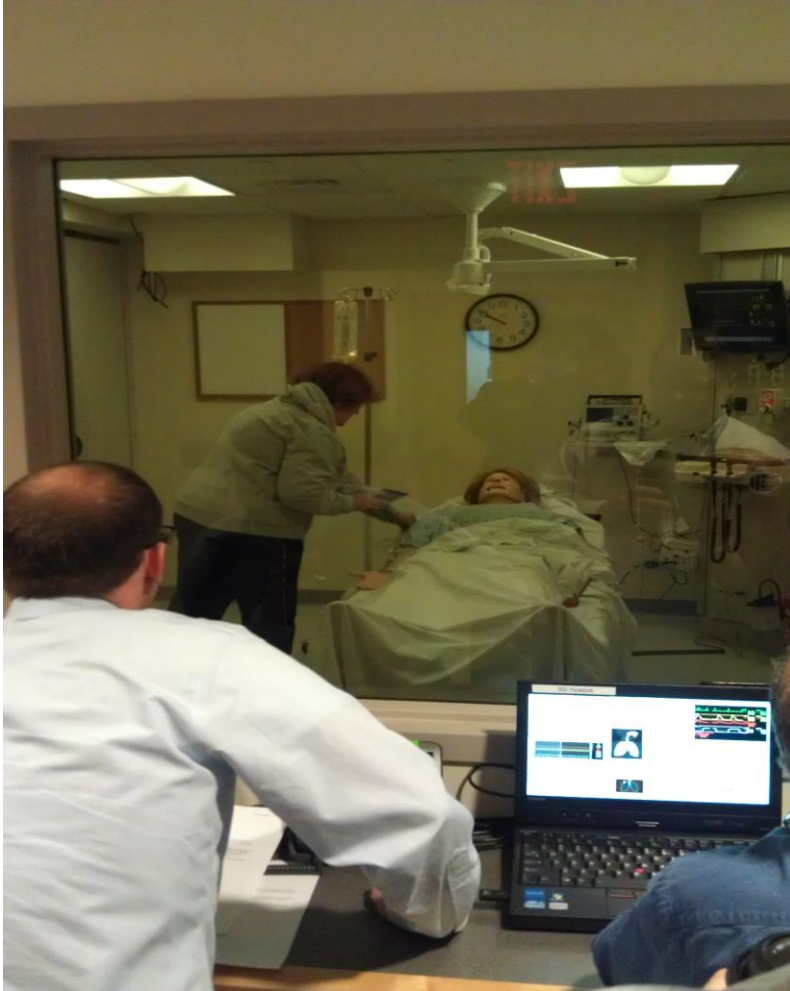
Adam Landman, MD, Stephen Miles, Pamela Neri, Anne Bane MPH, Micheal Sweet
Michael Dinsmorei

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(IT) API's and Schema.org

Patriot Boot Camp - Aneesh Chopra - TechStars

ECITL 2013; S_miles@mit.edu   2012 by Taylor McLemore

Open Supply Chain API's
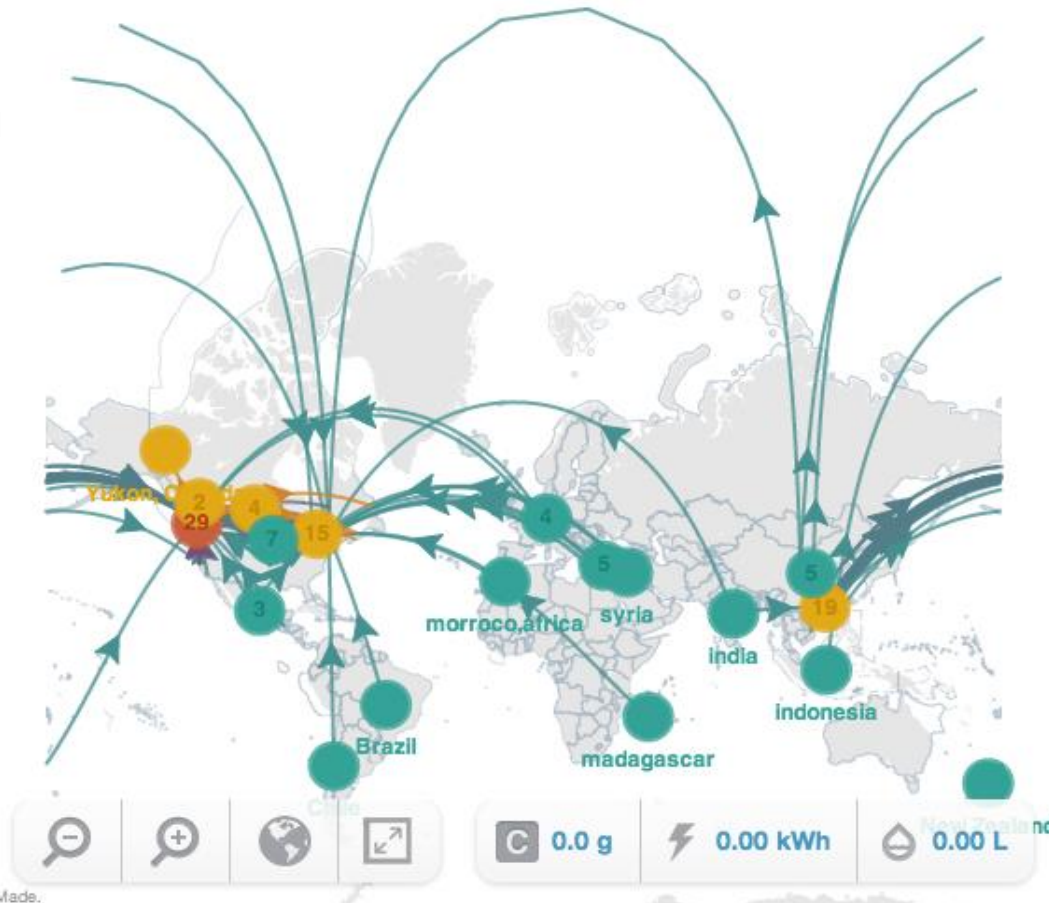
Ingredients

Spiceguy Sep 25, 2012

Leo Bonnani, MIT Media Lab PhD, SourceMap uses networks to **optimize industries and encourage ethical sourcing**. Using touchscreen displays, industry representatives pool information about their supply chains, plan economic development, supply chain ethics

10/24/2013

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http://sourcemap.com/view/3468

Thank you!

About Me:

- Research Affiliate, CBI

- Research Scientist, Auto-ID Labs

- Adjunct Research Professor, Zaragoza Logistics Center
  EC FP7 CASSANDRA Supply Chain Security Project

- Principal Consultant in Auto-ID Serialization and Event
  Management

- Member executive teams at IronBridge Networks, NMS
  Communications, Officenet, Computer Field Services

APPENDIX

BioAssay Research Database
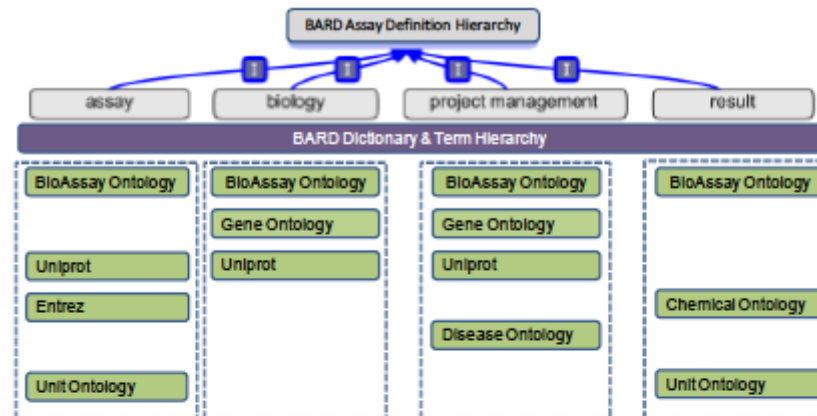
The use of authoritative, structured language enables queries and data mining not possible with unstructured, free-text assay descriptions or ambiguous terminology.

PubChem	BARD
Missing or fuzzy assay definitions, experiments and project concepts	Introduce assay definitions, experiments and projects
'Column header' centric with concentration details embedded	Result types and concentrations as experimental variables
Extensive use of unstructured text	Transition to structured use of common language

Semantic Markup - Rich Snippets


```
Microdata (schema.org)   RDFa   Turtle

<!-- on the payment info (or any other static) page, we define the
     non-standard payment method -->
<h1 itemscope itemtype="http://purl.org/goodrelations/v1#PaymentMethod"
    itemprop="http://schema.org/name"
    itemid="http://acme.com/payment/#giftcard">ACME Gift Card</h1>
...

<!-- on the offer page, indicate this payment option -->
<div itemscope itemtype="http://schema.org/Offer" itemid="#offer">
  <div itemprop="name">Hepp Technology Color TV</div>
  <div itemprop="description">This TV set is the ideal multimedia center
for your home</div>
  Payment:
  <a itemprop="http://purl.org/goodrelations/v1#acceptedPaymentMethods"
     href="http://acme.com/payment/#giftcard">ACME Gift Cards</a> or
  <link itemprop="http://purl.org/goodrelations/v1#acceptedPaymentMethods"
     href="http://purl.org/goodrelations/v1#Cash" />cash
<!-- other offer properties follow here -->
...
</div>
```

http://www.heppnetz.de/ontologies/goodrelations/v1.html

E-Freight Ontology as Good Relations?

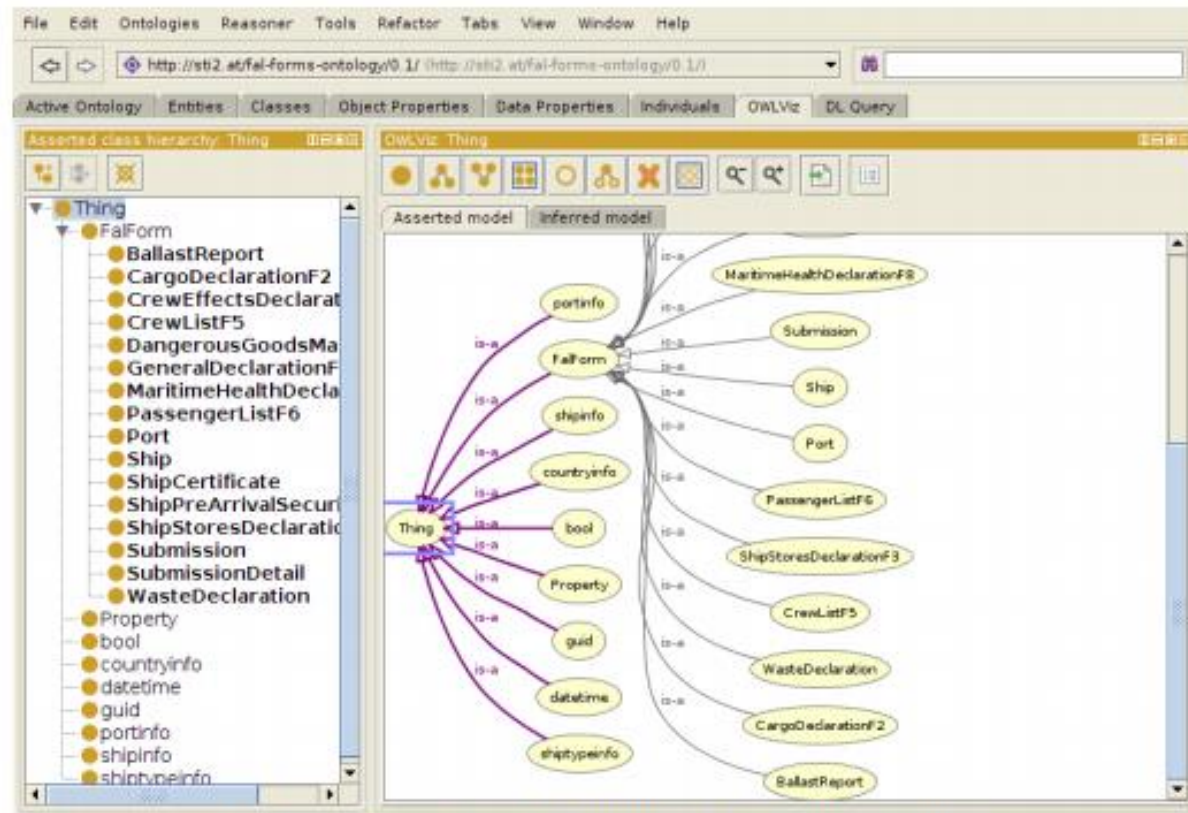Center for Biomedical Innovation

e-Freight D2.3 – The e-Freight Ontology

Figure 1: Screenshot of the Protégé ontology editor.