Securing the Drug Supply Chain

A Framework to Evaluate Interoperable Data Exchange Models
for Drug Supply Chain Security Act Compliance

Authors: Peter Chung, Tao Zhang
Advisor: André Carrel

MIT SCM Research FEST

May 19, 2016

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AGENDA

- BACKGROUND

- PROBLEMS

- CONTEXT

- METHODOLOGY

- RESULTS

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Embarrassment
&
Disappointment

Side Effects
&
Death

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BACKGROUND
Drug Security is Decreasing Globally

- North America
- Europe
- Africa
- Asia
- Middle East
- International
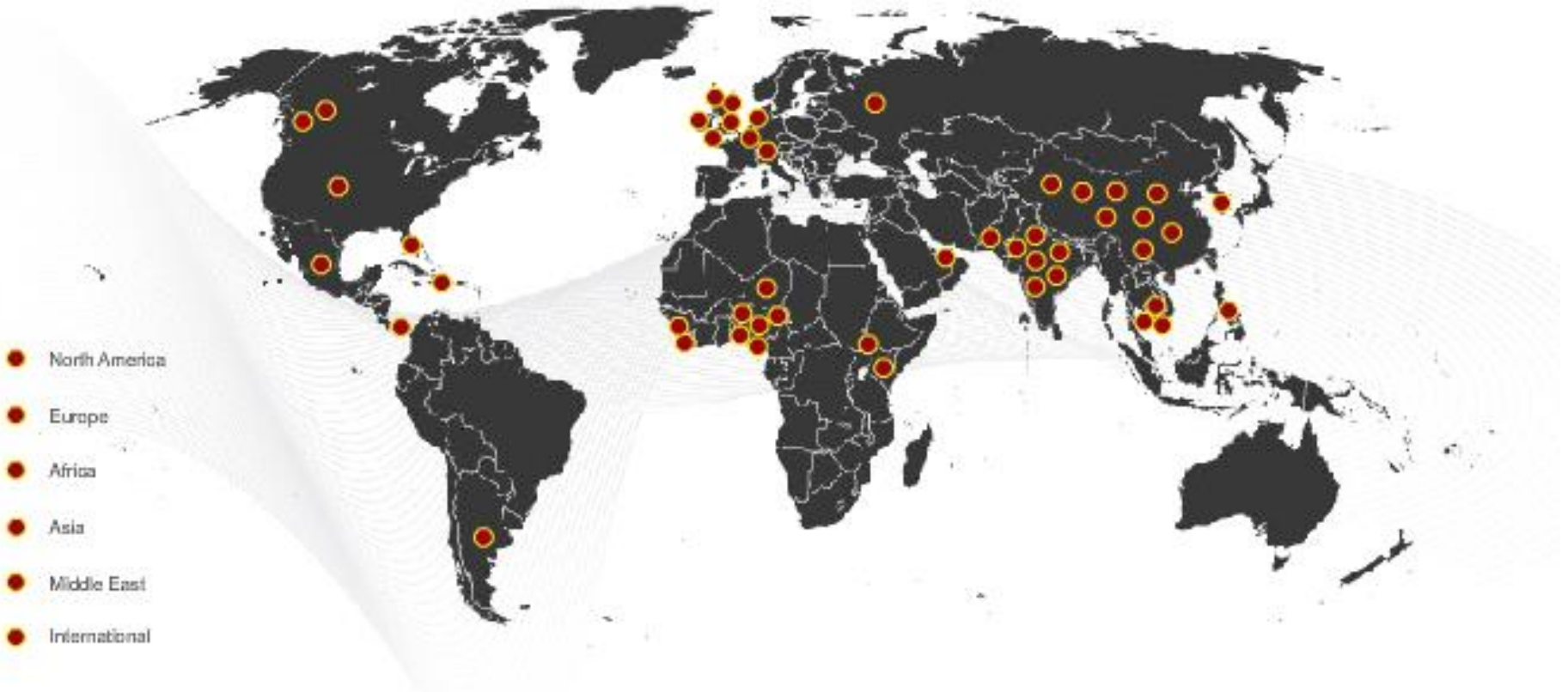
Source: Pharmaceutical Research and Manufacturers of America

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BACKGROUND
New Threats to the US Drug Supply Chain

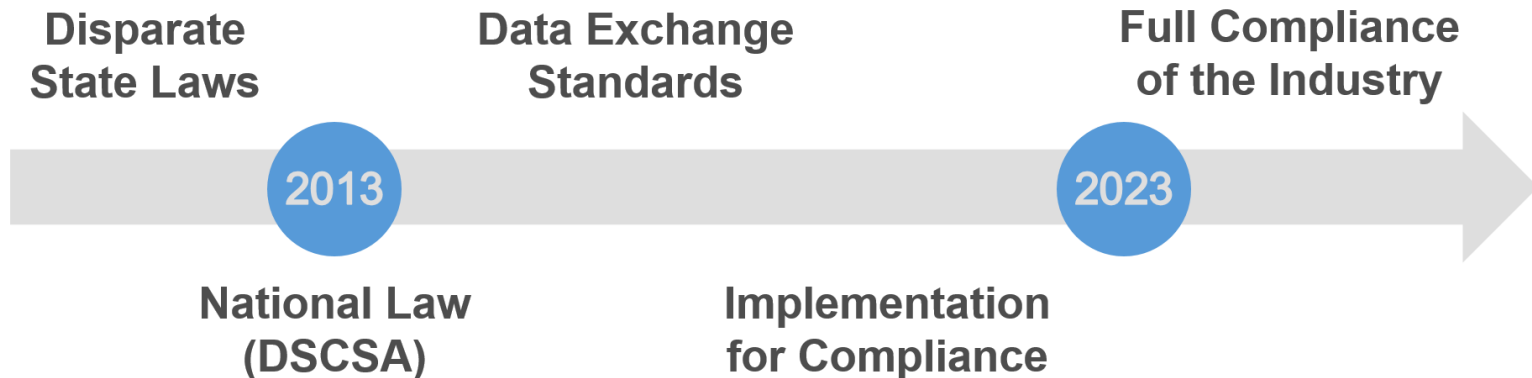### Challenges

> Counterfeit drugs
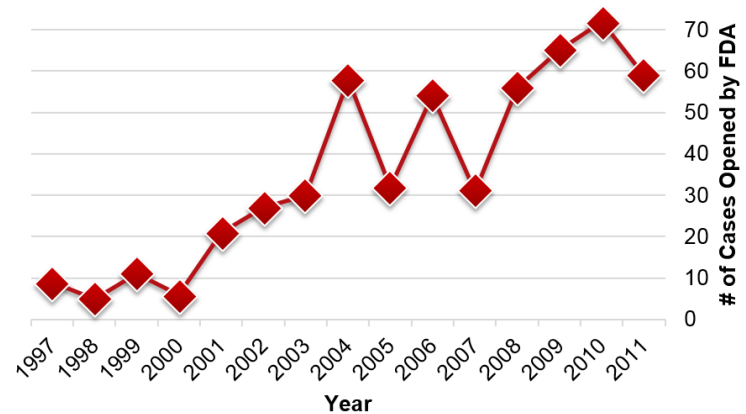
> Diverted/illegally imported drugs

> Online drug sales

Solution

Track and trace the smallest sellable unit of drug through the supply chain using serial numbers.

Counterfeit Drug Cases are Increasing

Timeline

Disparate State Laws

Data Exchange Standards

Full Compliance of the Industry

2013

2023

National Law (DSCSA)

Implementation for Compliance

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BACKGROUND
Information Flows of the Drug Supply Chain

AGENDA

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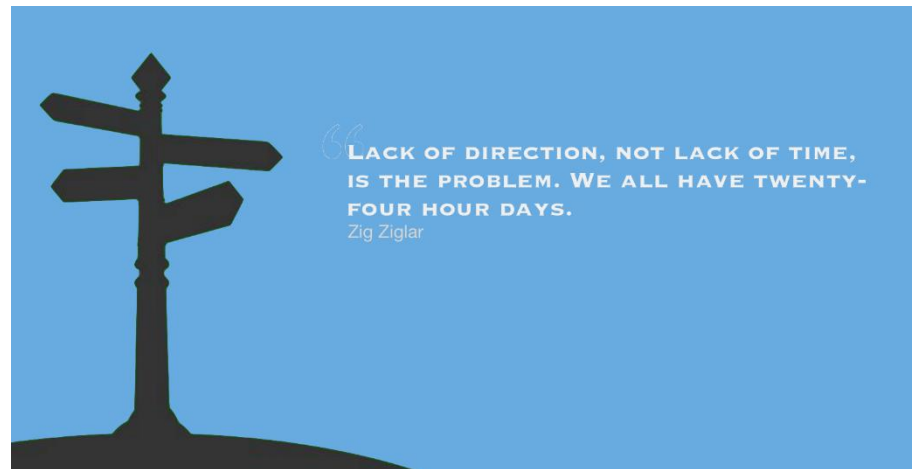
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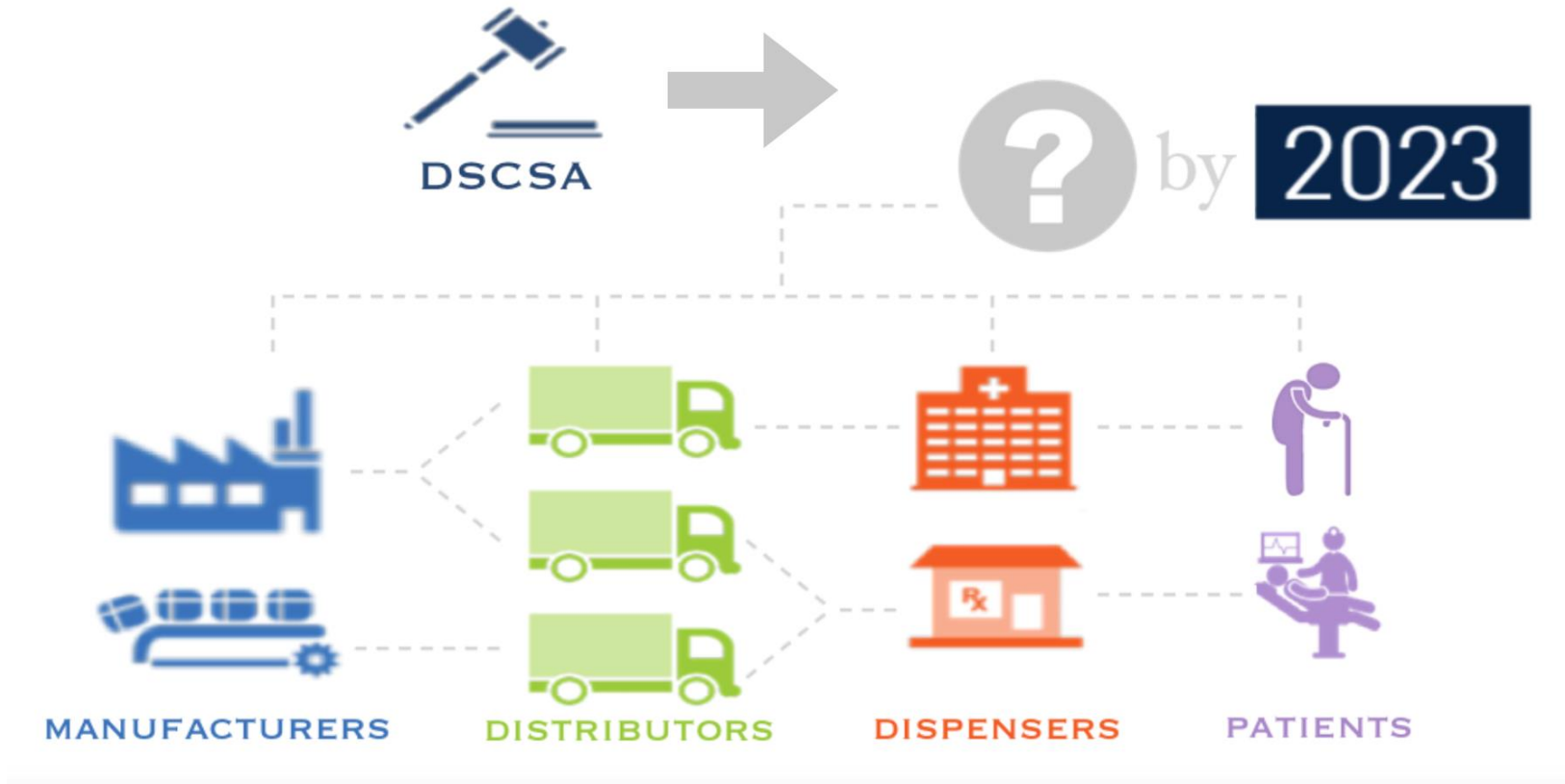
PROBLEMS

Numerous Options
> Existing solutions from other countries
> Proposals from domain experts

Multiple Stakeholders
> Manufacturers
> Distributors
> Dispensers
> Patients
> Various Governments

Limited Data
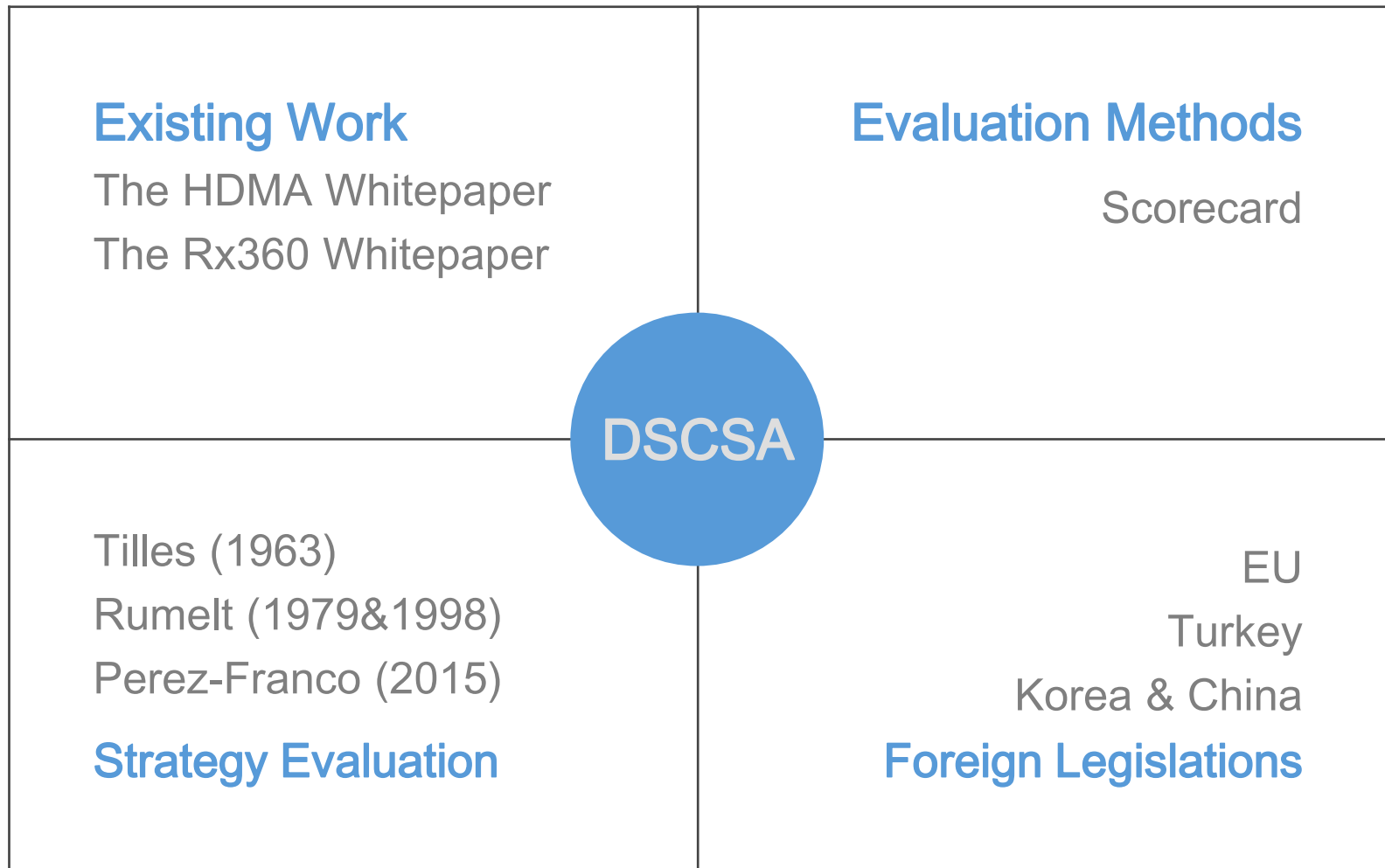> About operational costs
> From all stakeholders

"LACK OF DIRECTION, NOT LACK OF TIME, IS THE PROBLEM. WE ALL HAVE TWENTY-FOUR HOUR DAYS.
Zig Ziglar

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Context

Existing Work

The HDMA Whitepaper
The Rx360 Whitepaper

Evaluation Methods

Scorecard

DSCSA

Tilles (1963)
Rumelt (1979&1998)
Perez-Franco (2015)

Strategy Evaluation

EU
Turkey
Korea & China

Foreign Legislations

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METHODOLOGY
Overview

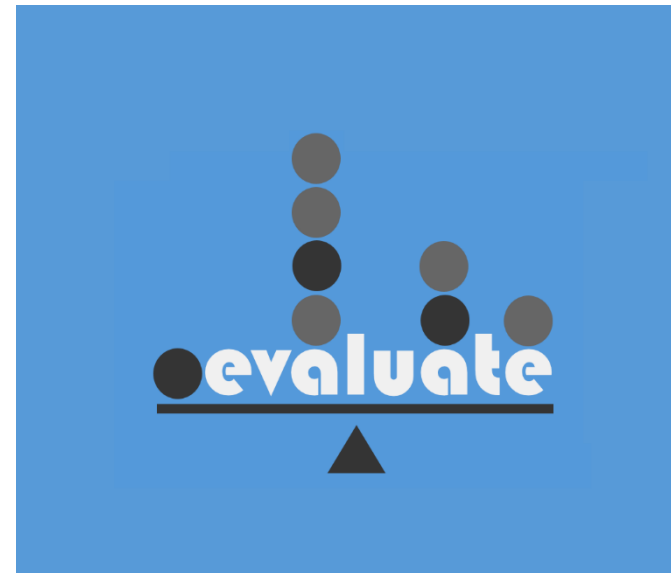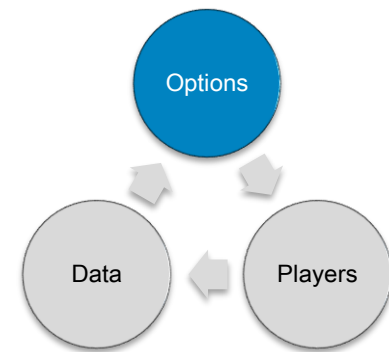| Problems	Solutions
Numerous Options	Picking One out of Many
Multiple Stakeholders	A Holistic Approach for Individual Challenges
Limited Data	Qualitative Analysis of Quantitative Metrics

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METHODOLOGY
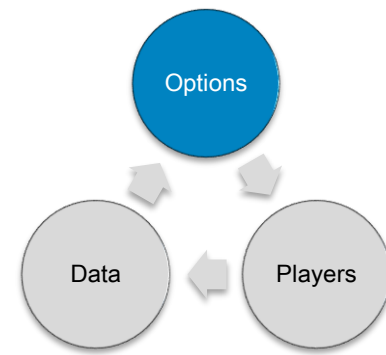## Picking One out of Many

Categorize for Simplicity

Three types of models
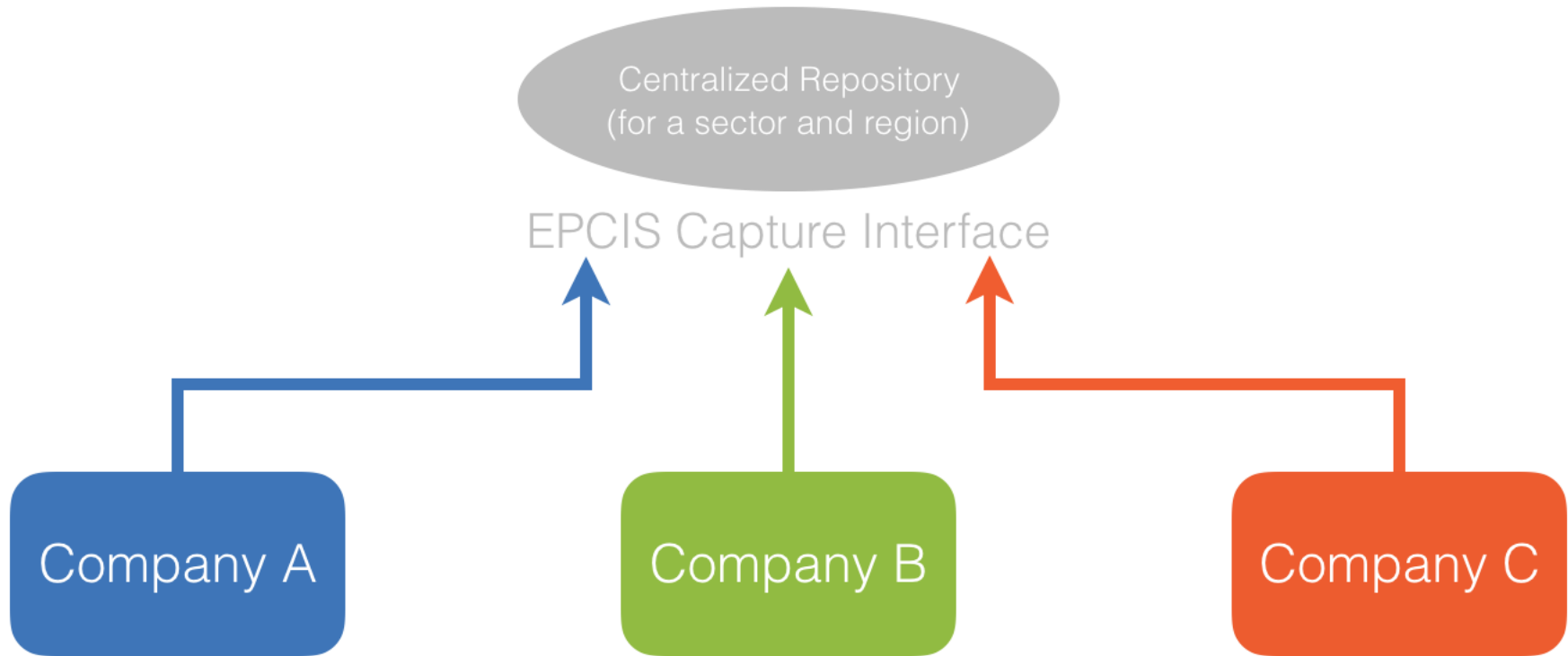
> Centralized

> Semi-centralized

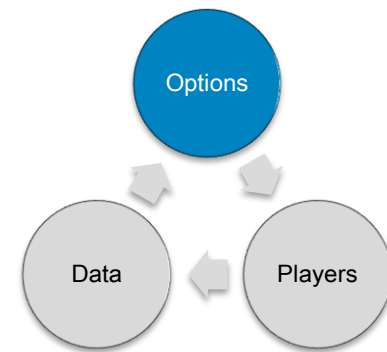> Distributed

METHODOLOGY
Picking One out of Many

Centralized

Centralized Repository
(for a sector and region)

EPCIS Capture Interface

Company A   Company B   Company C

Options

Data   Players
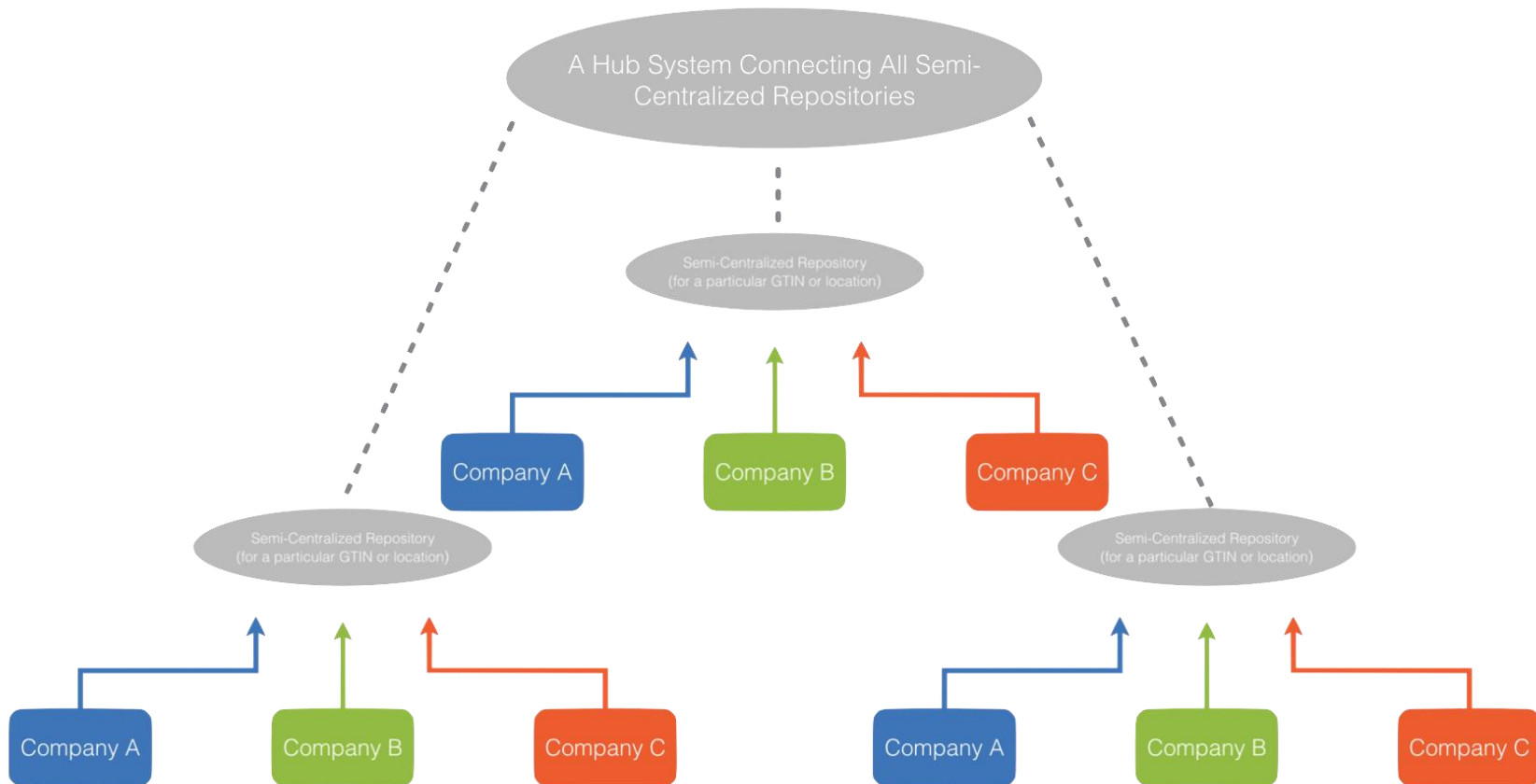
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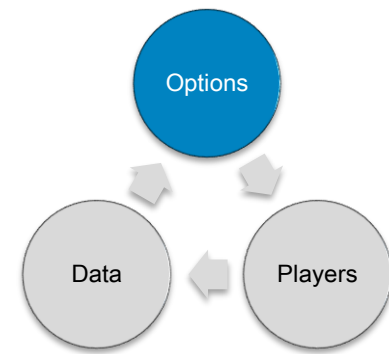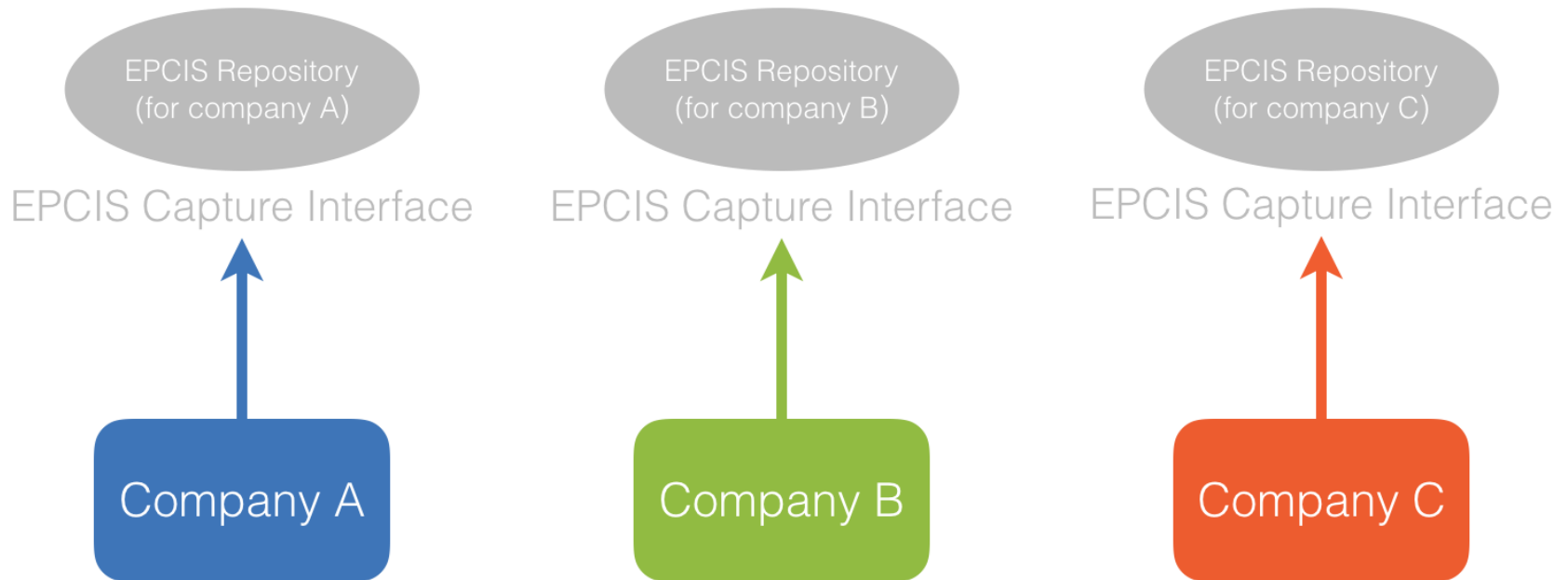## Picking One out of Many

Semi-centralized

METHODOLOGY
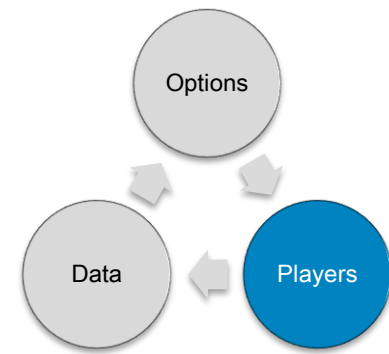## Picking One out of Many

Distributed

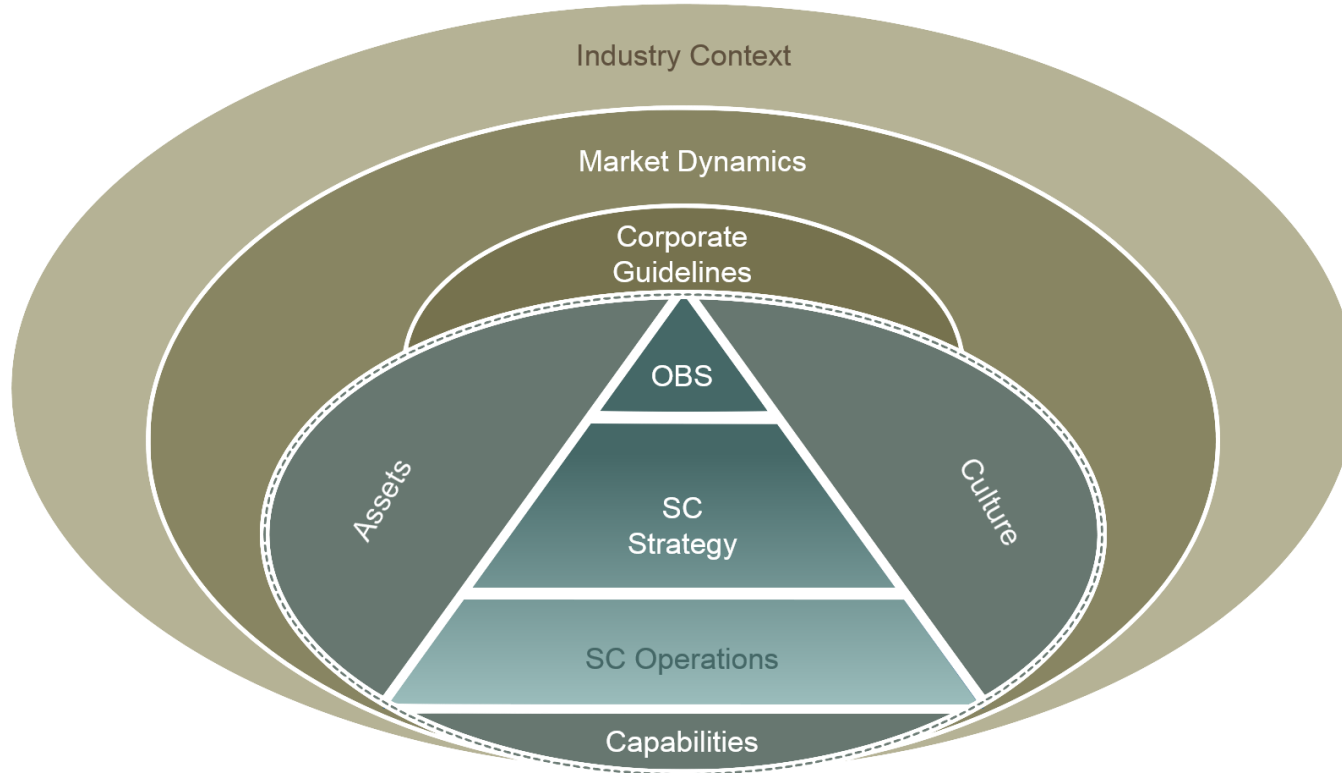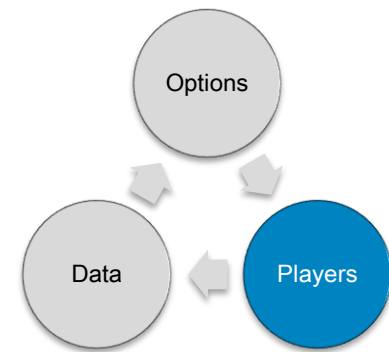# METHODOLOGY
A Holistic Approach for Individual Challenges

Consolidate concerns from all stakeholders

> Allow information sharing for **compliance**

> Enhance the **operational efficiency**

> Improve patient **safety**

> Protect customer **privacy**

> Balance **international** regulations

COSPI

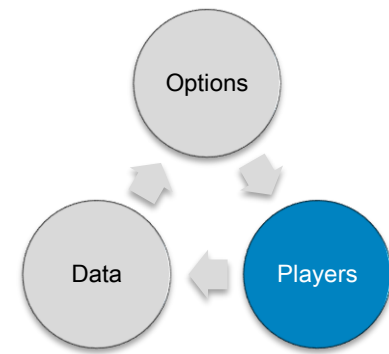**MIT** Supply Chain
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METHODOLOGY
A Holistic Approach for Individual Challenges

Guide the decision using an extensive framework – SC2020

METHODOLOGY
A Holistic Approach for Individual Challenges

	Compliance	Operational efficiency	Security	Privacy	International compliance
Company goals and capability	X	X	X	X	X
Corporate guideline	X		X	X	
Market dynamics		X	X	X	X
Industry context	X		X	X	X

High overlap between COSPI and SC2020

METHODOLOGY
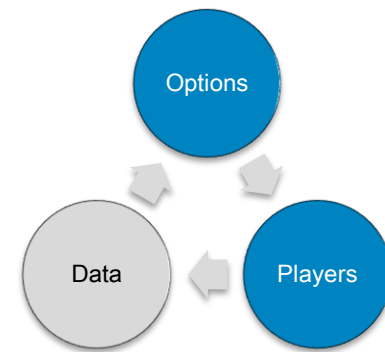## A Holistic Approach for Individual Challenges
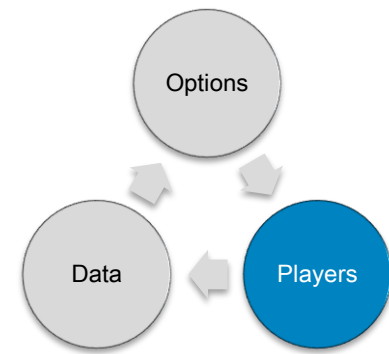
Mapping Shared Concerns
to Required System Capabilities

COSPI	7 Scenarios	26 Capabilities	4 Types

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METHODOLOGY
Putting Options and Players Together

Options and Players in One Scorecard

Stakeholders	Required Capabilities	Type	Central-ized	Semi-centralized	Distributed
Manufacturer, Distributor and Dispenser	Disclose the information based the information requester's privacy access level	A			
	Grade the privacy level of the submitted information	A			
	Make serialization data available to verify the authenticity of the drug when the drug is shipped	W/S			
	Make sure the verification interface is not compromised (e.g. hacked by fake dealers so that fake drugs can be verified as authentic ones)	W/S			
	Map serial number to pallet/case number	R			
	Map serial number to the storage space/retail branch	R			
	Provide transaction information when transferring ownership	W/S			
	Record investigation history	W/S			

METHODOLOGY
Qualitative Analysis of Quantitative Metrics

Options

Data

Players
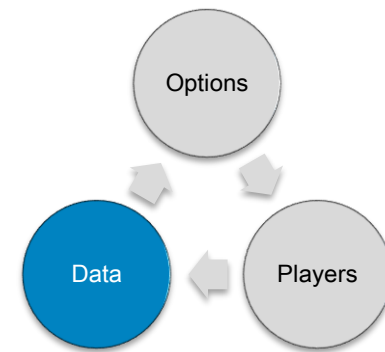
Two Types of Costs

> Fixed / Upfront

> Variable / On-going

Qualitative Scores

> Relative favorability

> Non-proportional

> Non-representative

		Variable / On-going Cost			
		No on-going maintenance effort needed	Need maintenance effort from an individual company	Need maintenance effort from multiple companies and the coordinator is obvious	Need maintenance effort from multiple companies but the coordinator is not obvious
Fixed / Upfront Cost	Has cost sharing synergy	5	4	3	2
	No cost sharing synergy	4	3	2	1

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RESULTS

Semi-Centralized Model

> Highest evaluation score

> A balanced mix of flexibility and cost-sharing synergy

Q&A