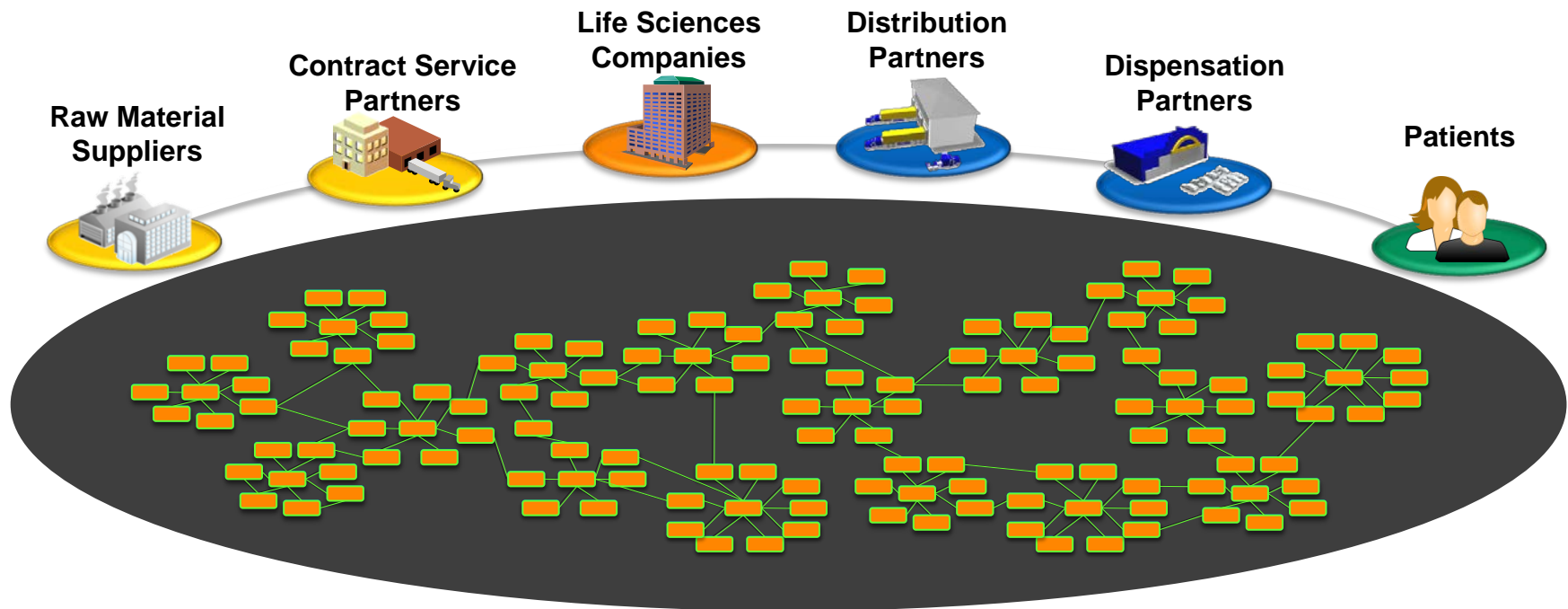


Supply, Capacity and Quality in the Virtual Pharmaceutical Supply Chain

Shabbir Dahod
President and CEO
TraceLink Inc.



The Life Sciences Business Network powered by TraceLink



TraceLink is revolutionizing the Life Sciences Business Network by bringing point and click collaboration and information exchange to teams working across multiple enterprises

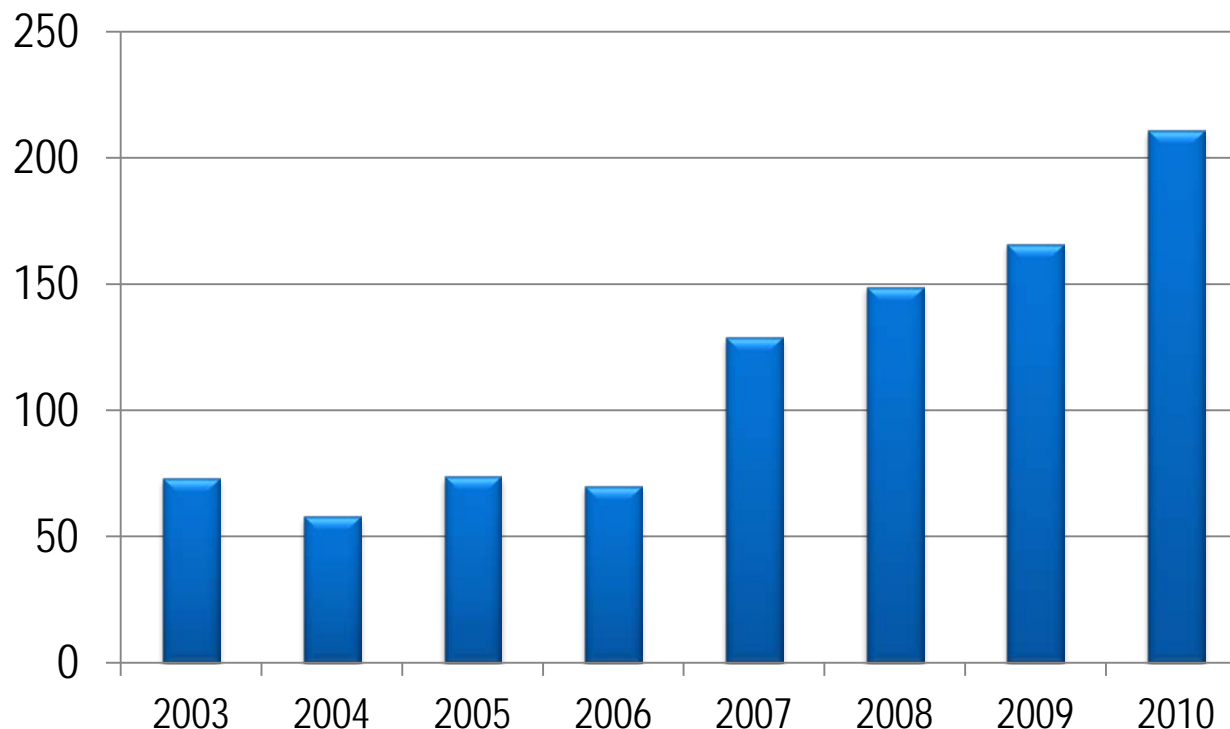
Session Topics

- Factors driving the shift from a vertical business model to a virtual execution model
- Business issues and operational challenges created as production is outsourced
- Taking a network approach to life science supply collaboration
- The required collaborative business network architecture for visibility, accountability and control
- Opportunities to improve supply, capacity and quality control in a collaborative supply network

Supply, Capacity, Quality Issues

Out of Stocks

New Drug Shortages (US)



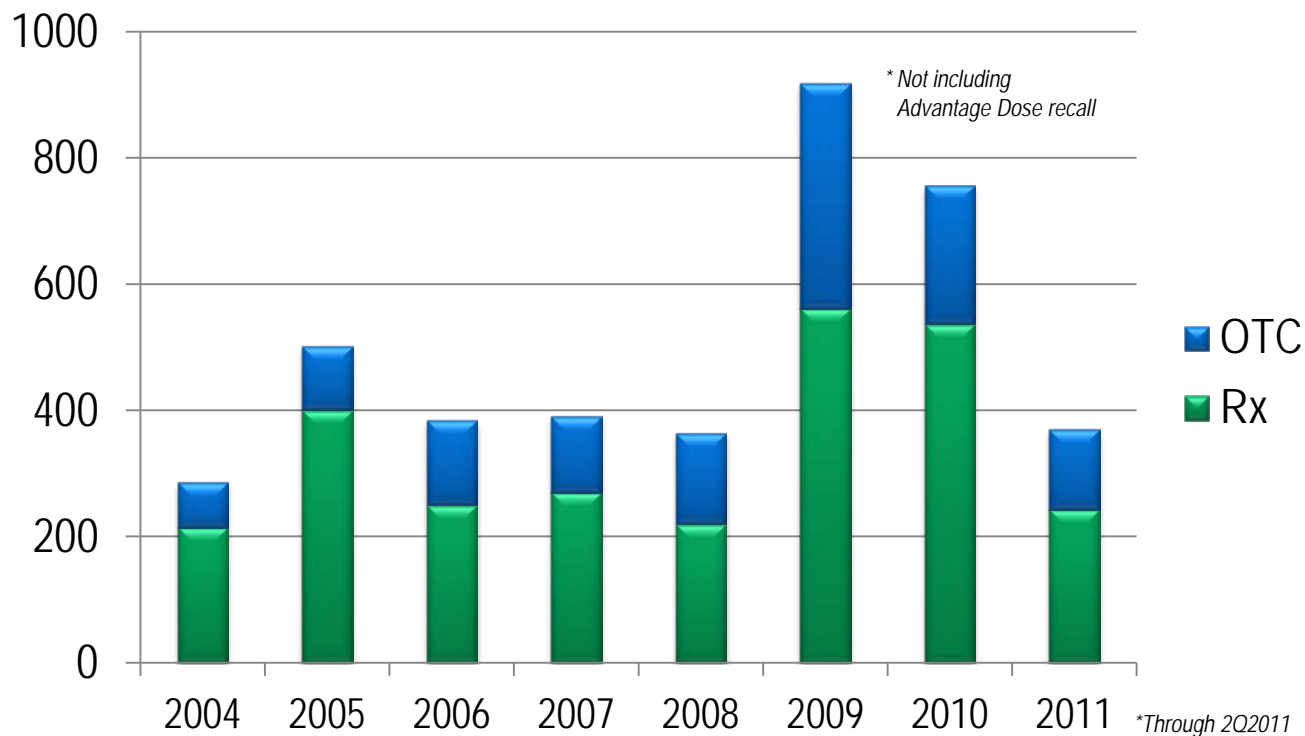
Source: University of Utah Drug Information Service

- Product Quality
- Shipment Delays / Capacity Constraints
- Discontinuation
- Raw Materials (API) Issues
- Loss of Manufacturing Site
- Component Problems / Shortage

Supply, Capacity, Quality Issues

Product Recalls

Product Recalls in US



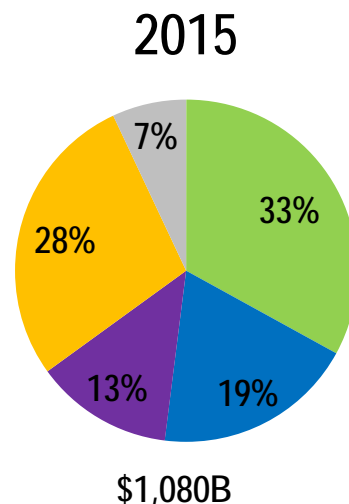
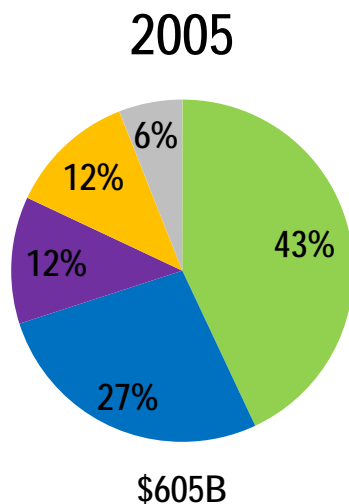
Source: FDA

- Manufacturing (temp, contaminants)
- Manufacturing (cGMP)
- Packaging Issue (labeling)
- Adverse Event

Supply, Capacity, Quality Issues

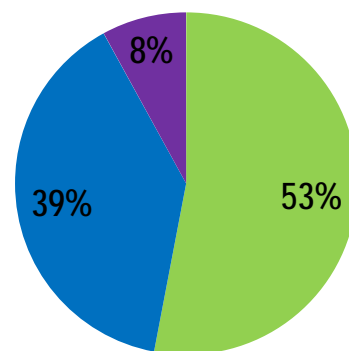
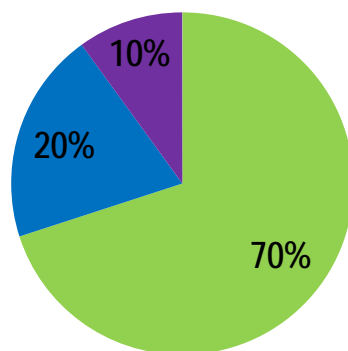
Globalization and Diversification of Demand

Global Demand



- US / Canada
- Europe
- Japan / S. Korea
- Pharmerging (Brazil, Russia, India, China)
- Rest of World

Product Type Demand



- Brand
- Generics
- OTC / other

Patent Expiry = \$120B (2011 – 2015)

Source: IMS Market Prognosis May 2011

Supply, Capacity, Quality Issues

Serialization and Traceability Regulations

2010 2011 2012 2013 2014 2015 2016

Regulatory Actions



Italy, Belgium, Greece, Turkey: pre-existing regulations in force



US FDA Standardized Numeric Identifier (SNI) guidance



Serbia Traceability pilot



US FDA Track and Trace Workshop



France: CIP13 labels; 2D barcode



EU: Serialization directive vote



Turkey: Phase 2 full aggregation



India: Export barcoding

India: Domestic serialization guidance



China: Phase II Essential Drug List



UK: NHS supplied products with GS1 identifier on package



Canada: GTIN-based labeling



Brazil: Reg 11.903 serialization (expected)



South Korea: KDC labels on all Rx (ex-orphan drugs)



Canada: National Product Registry live



US: CA Phase 1



US: FDA (expected)



China: All locally produced drugs (expected)



US: CA Phase 2



EU: Serialization implementation across members states

Industry Requirements



Italy, Belgium, Greece gov't reporting



Turkey gov't reporting



France gov't reporting



China gov't authentication



Brazil gov't authentication



Brazil gov't reporting



Canada product registry synchronization



CA product serialization and ePedigree



FDA authentication

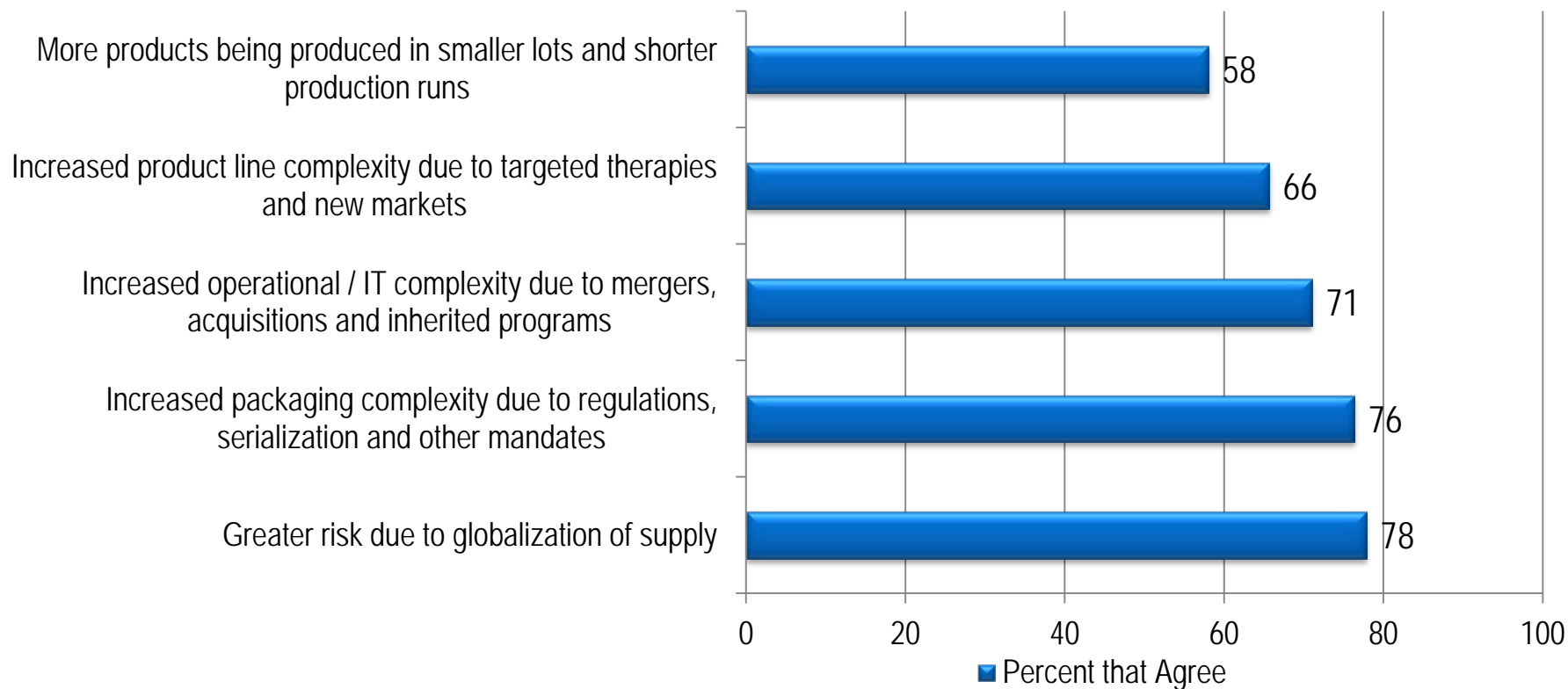


EU EQDM authentication

The Result: Complexity and Risk in the Supply Chain

Strategy, Planning and Execution

What Issues Impact Your Supply Chain Strategy, Planning and Execution?



Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences

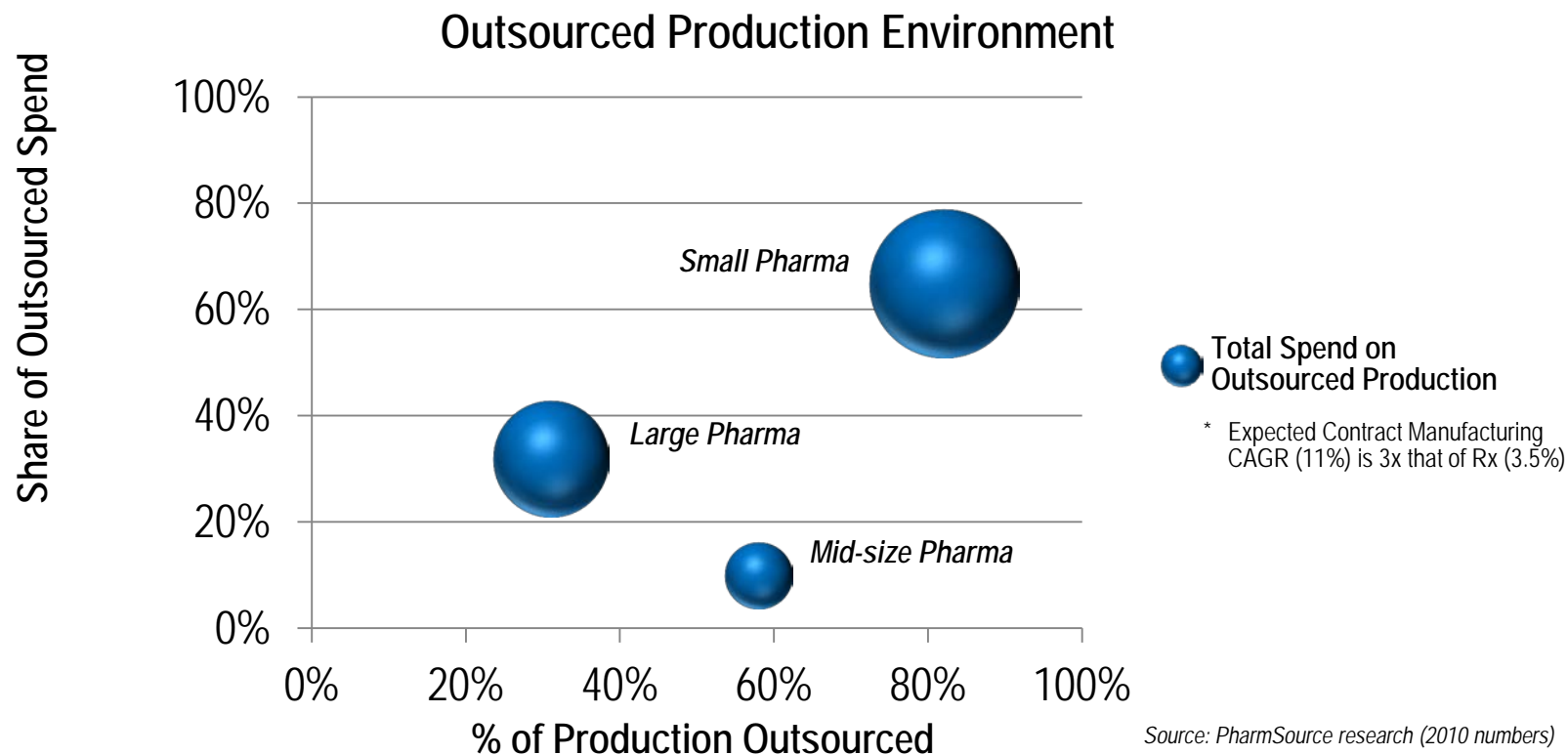


Tight cash flow is all well and good when you have high forecast accuracy and consistent demand. But, in the last 5 years, our portfolio has increased to ten different SKUs per product line with massive expansion into new markets that have poor forecast accuracy and considerably smaller sales volumes.

Top 10 PharmaCo

Outsourced Production is Growing in Response

Flexible Capacity, Market Access, Increased Capabilities

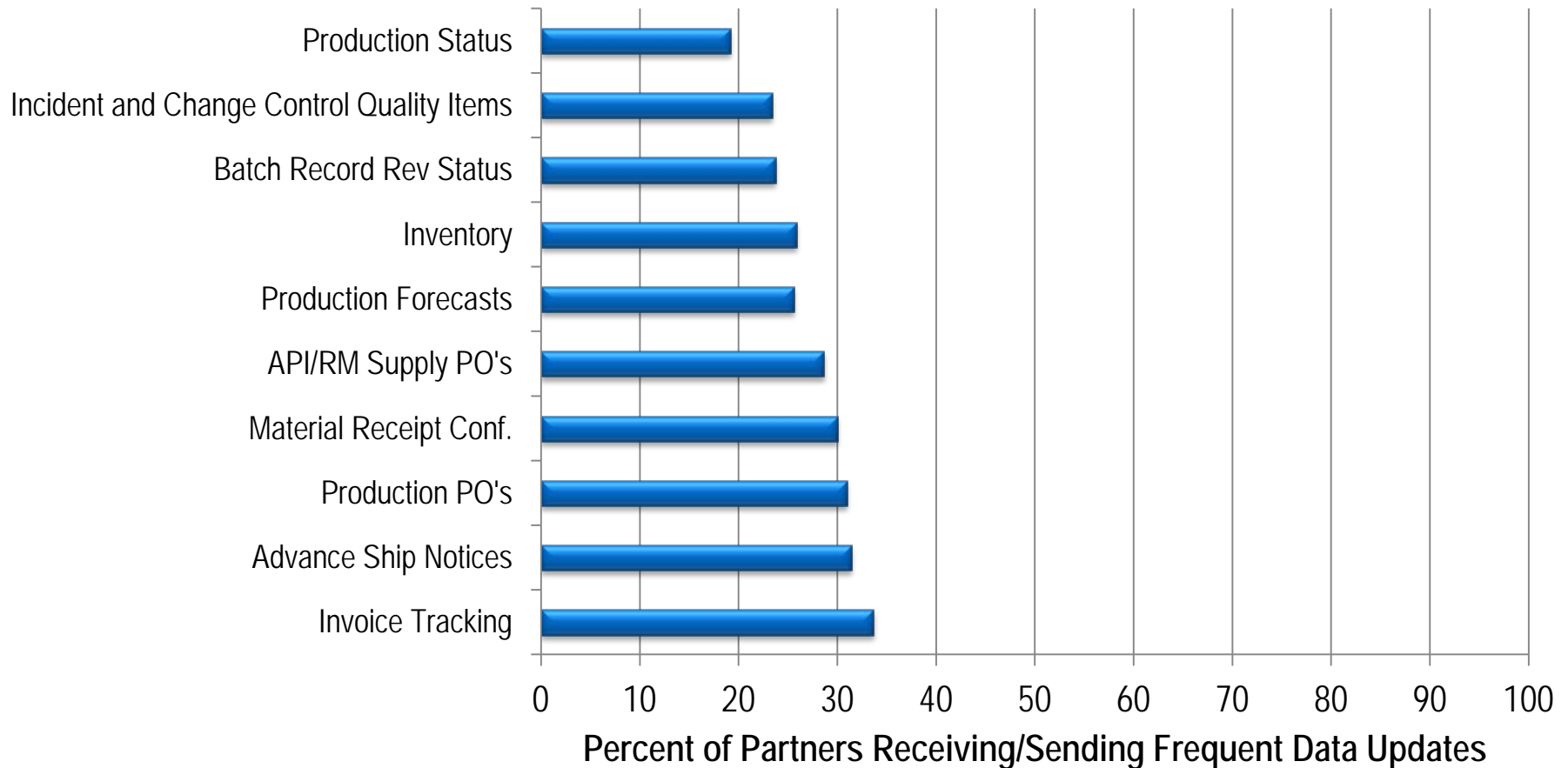


By 2012, 32% of pharmaceutical manufacturing output is expected to be produced by third parties.

Hussain Mooraj – Managing VP **Gartner**

Availability of Timely and Accurate Data for Outsourced Production Management is Lacking

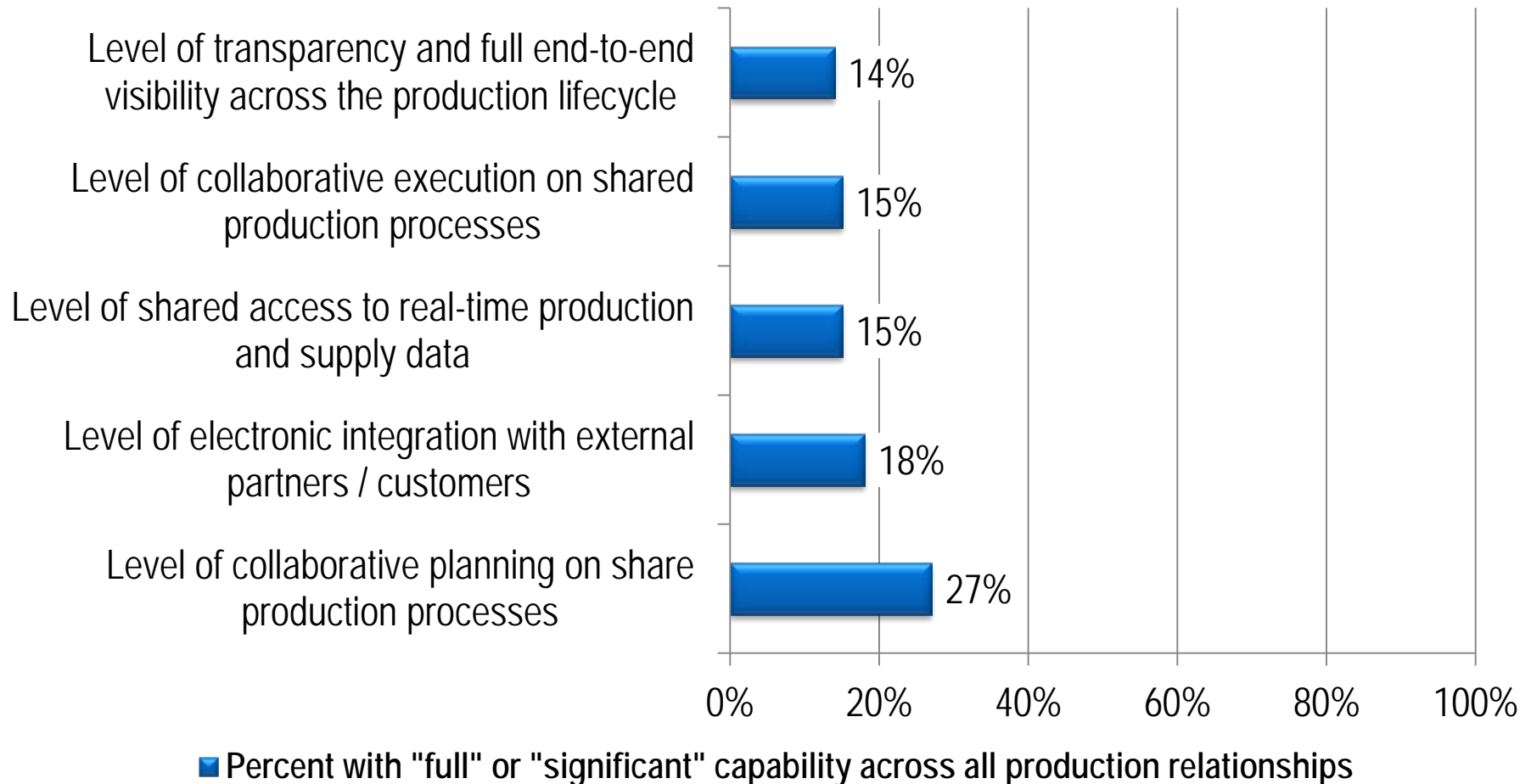
Level of Information Sharing in the Supply Network



Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences

Process and Transaction Collaboration is Limited

Level of Visibility and Collaboration in Outsourced Production



Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences

Ensuring Supply, Capacity and Quality Requires a Network Approach

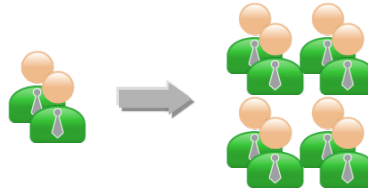


- Dozens of interconnected processes (orders, production runs, quality reviews, inventory management, distribution...)
- Between tens of thousands of companies (material suppliers, CMO/CPO, pharma/bio, distributors, pharmacies/clinics ...)
- With data flowing between millions of links (forecasts, orders, production status, inventory levels, product flows, ID authentications...)
- For billions of products moving between nodes (pharmaceuticals, OTC drugs, clinical kits, bulk materials, packaging supplies...)

Approaches for Improving Supply Network Connectivity and Collaboration

1

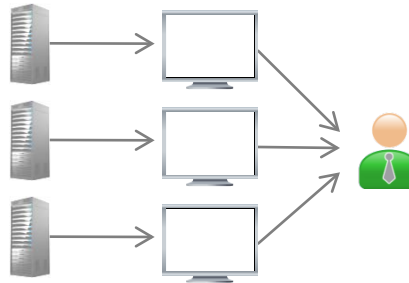
Add More People



- Poor integration with core systems
- Manual data entry
- Low data exchange frequency
- No collaborative view
- Labor intensive

2

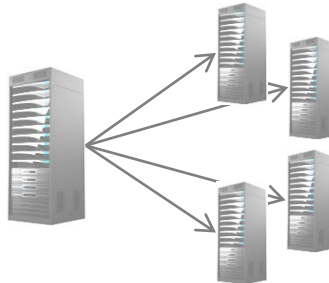
Push Data into Portals



- Partial integration with core systems
- Manual data entry
- Low data exchange frequency
- No collaborative view
- Increased partner complexity, work

3

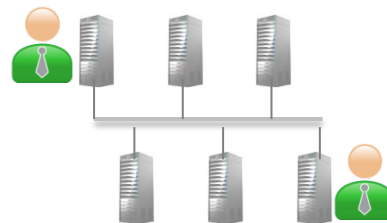
Expand Point-to-Point Integration



- Integrated with core systems
- Complex, translated data integration
- High exchange frequency
- No collaborative view
- IT intensive (per-partner setup, mgmt)

4

Integrate Once With a Business Network



- Integrated with core systems
- Native data integration
- High exchange frequency
- Collaborative view
- Single set-up, self-managed

The Required Collaborative Business Network Architecture

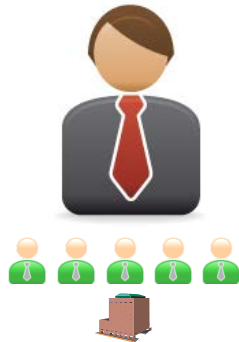
Connectivity • Visibility • Collaboration • Measurement



- ④ Providing real-time analysis of all product, production and channel performance
- ③ Enabling virtual teams from multiple companies to collaborate across business activities
- ② Delivering visibility and timely business data for a company's business network activities
- ① Simplifying integration to a company's entire business network through a single connection

The Collaborative Architecture Provides Monitoring, Measurement and Control of Outsourced Production

Life Science Company



Collaborative Supply Network Dashboard

Search					
●	FluMed	fm1234	122	276889	PharmaCo
●	FluMed	fm4567	122	276889	CMO-US
●	AllergyMed	am1234	122	276889	PharmaCo
●	AllergyMed	am4567	122	276889	CMO-EU
●	SleepMed	sm1234	122	276889	PharmaCo
●	SleepMed	sm4567	122	276889	CPO
CMO-US	92.5%				
CPO	96.6%				



Collaborative Team Workspaces

On-time
Delivery

Prod. cycle
time

Instrumented KPI Dashboards

Right-first-
time

Inv. levels,
expiry

Production

Materials

Integrated Business Processes

Quality

Inventory

Notes

Connected Communication Trail

Docs

IDoc

QDoc

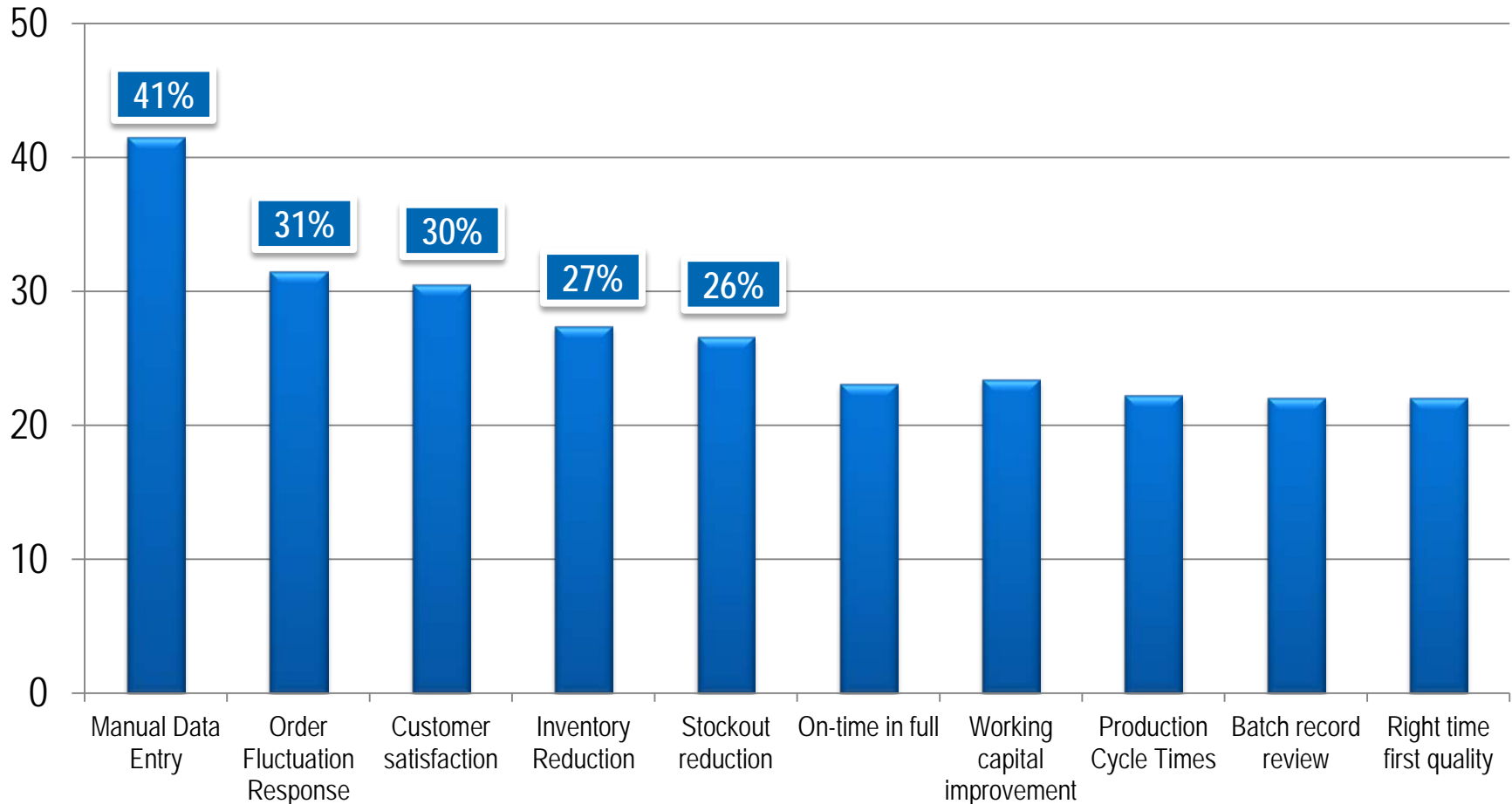
Integrated Data Exchange

X12

XML

A Collaborative Business Network Improves Control Over Supply, Capacity and Quality

Estimated % Improvement with a Collaborative Supply Network



Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences

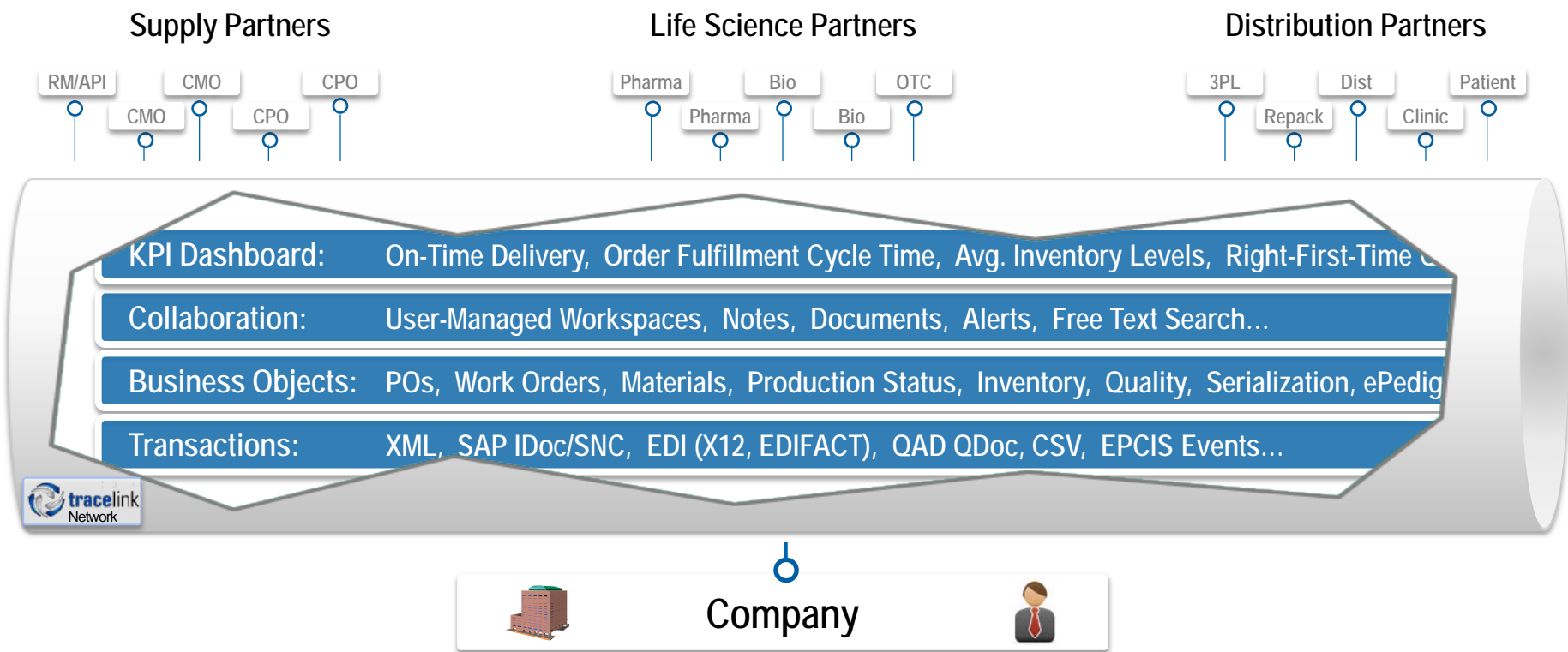
Supply Collaboration Equals Direct Financial Gain

Example: Quality Review Collaboration for One Product Line



TraceLink Network

Network Application for Connection, Data Sharing and Collaboration



- Information exchange platform providing single point of integration, transaction management and data sharing for all supply relationships
- Integrated, cross-linked business objects providing visibility across the production lifecycle and throughout the distribution channel
- Collaborative workspaces connecting users, improving communications and providing access to data on status, activities and performance
- Per-partner KPI dashboards providing real-time information about on-time delivery, production cycle time, etc.



Questions