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Role of Technology in Commercial Risk Management and Compliance

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A Few Topics for Today

- Introduction
- Examples of Commercial Risk Management and Compliance Issues
- Potential to Apply Technology

Intro to Edge Dynamics: Channel Commerce Mgmt Solutions to Pharma Manufacturers

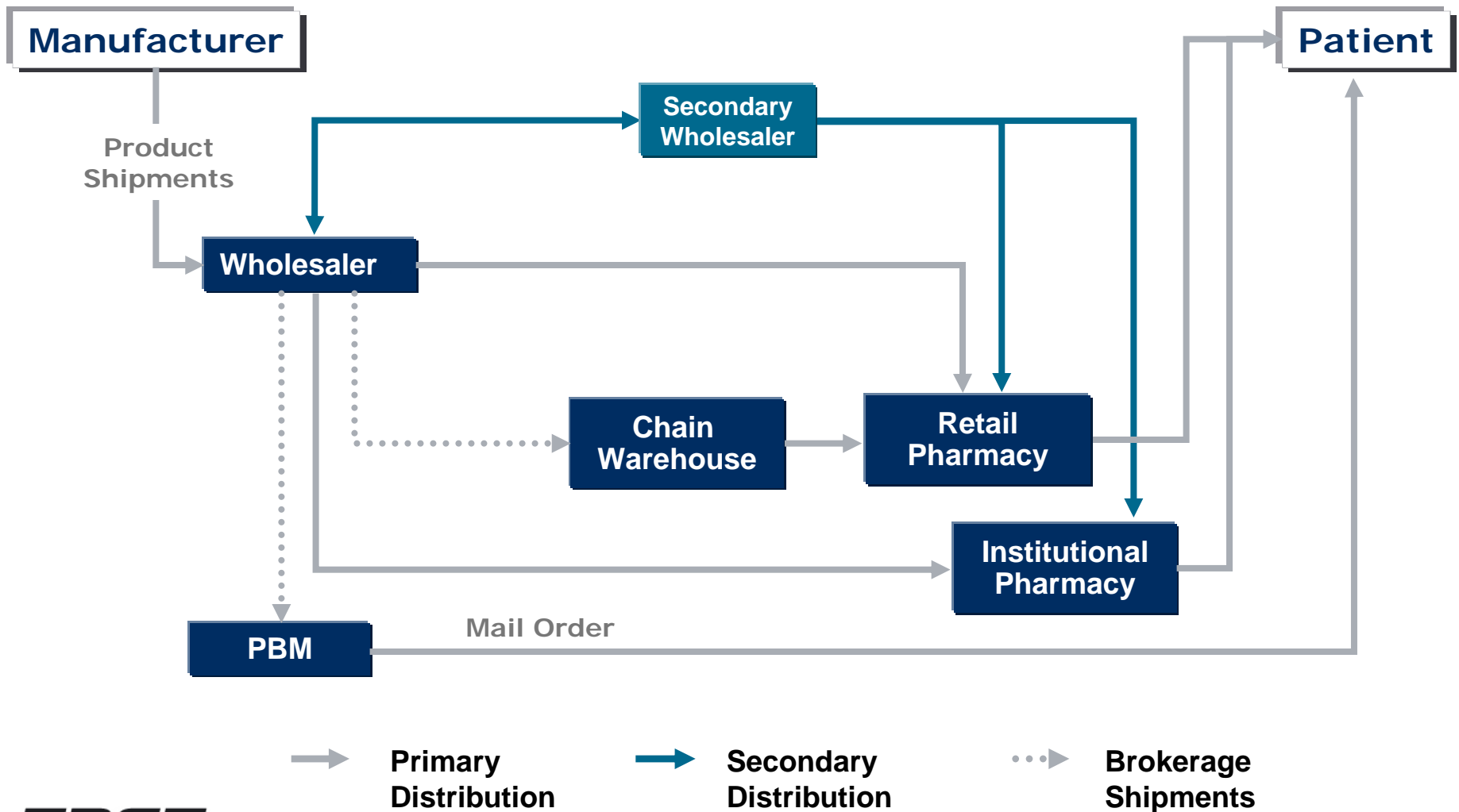
Selected Customers



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The Pharma Distribution Channel: Complex Flows of Product, Money, Information



Channel Commerce is a Foundation for Corporate Performance

Robust channel commerce requires transparency, accountability, control

and can enable improvements in:

Financial Performance

Regulatory Compliance

Market Integrity / Patient Safety

Commercial Operations Compliance Examples

- SarbOx Comp & Audit
- SEC Reporting
- FASB adherence
- Government Pricing
 - Medicaid Drug Rebate
 - Federal Supply Schedule
 - Veteran's Health Care Act
- Chargebacks and Returns
- Channel Agreements
 - WDA, IMA, DSA, FFS
- Controlled Substances
- Pedigree
 - FDA PDMA
 - State Laws

Key Pharma Channel Commerce Challenges

	Performance	Compliance	Integrity
<i>Key Drivers</i>	Agreements <ul style="list-style-type: none"> Channel inventory control Revenue predictability Revenue leakage - speculation, returns, chargebacks Channel service levels Supply chain efficiency 	SarbOx <ul style="list-style-type: none"> SEC reporting (10-Q, 8-K) SarbOx controls (404 compliance) FASB policies (revenue, accruals) Policy enforcement at transaction level Auditable channel data repository 	Brand Protection <ul style="list-style-type: none"> Channel data quality Secondary market activity Counterfeit drug distribution Integration with existing and future pedigree standards Granular data usage (867, 856, lot#, RFID)
<i>Key Benefits</i>	0.25-1.5% Net Revenue Increase	Financial and Audit Risk Reduction	Patient and Brand Risk Reduction

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Non-Compliance can be Expensive

King Pharmaceuticals Reports Year-End and Fourth-Quarter 2005 Financial Results

"During the fourth quarter of 2005, net sales of the Company's key branded products were adversely affected by approximately \$30 million resulting from changes in wholesaler buying patterns. The data upon which the Company relied and based its original third-quarter 2005 estimates of wholesale inventory levels was incorrect due to reporting errors made by two of the Company's major wholesale customers.



Non-Compliance can be Expensive

06-15-05 -- Bristol-Myers Squibb -- Agreement -- News Release

Bristol-Myers Squibb Charged with Conspiring to Commit Securities Fraud; Prosecution Deferred for Two Years

- Two Former Company Execs Indicted -

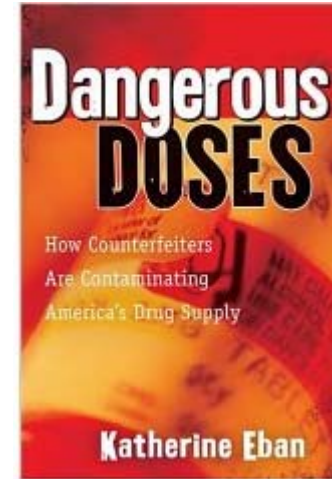
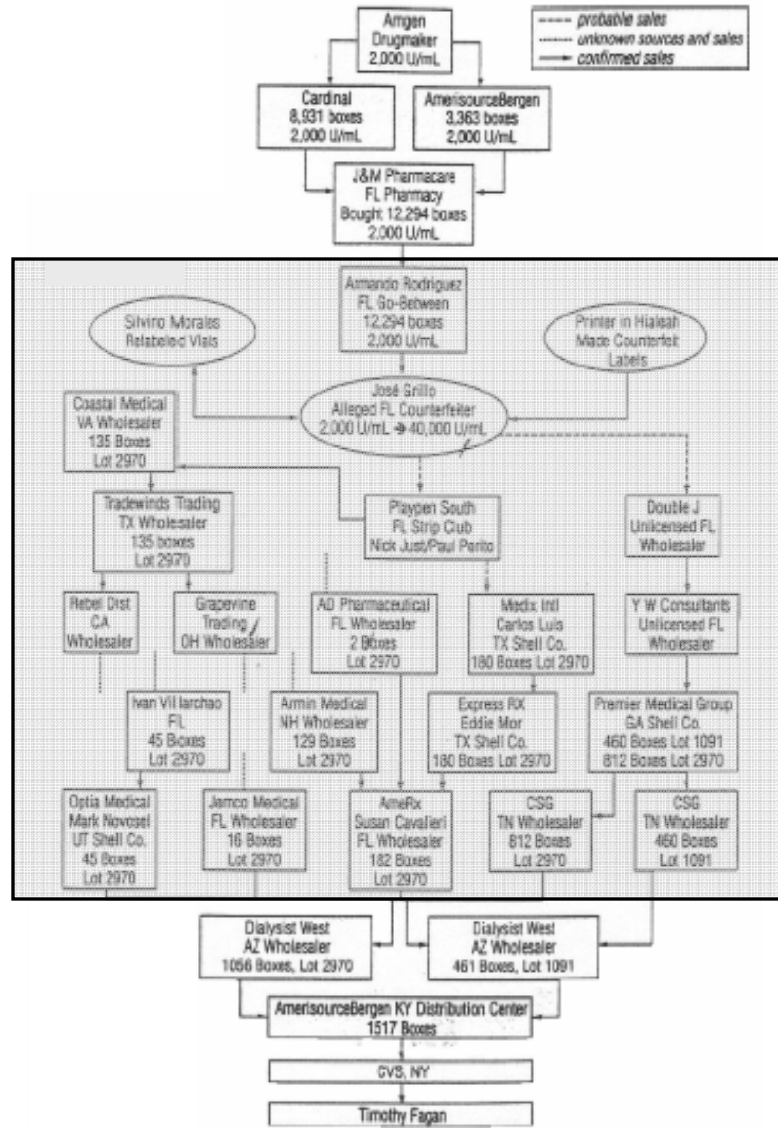
NEWARK - Bristol-Myers Squibb Company (BMS) has agreed to pay an additional \$300 million in restitution and undertake a series of corporate reforms as part of an agreement with the government to defer prosecution on a charge of conspiring to commit securities fraud for the company's failure to disclose its "channel-stuffing" activities in 2000 and 2001, U.S. Attorney Christopher J. Christie announced.



\$839M in fines

Counterfeiting - By-Product of Poor Channel Control

Manufacturer
 National Wholesaler
 Pharmacy
 Gray Market



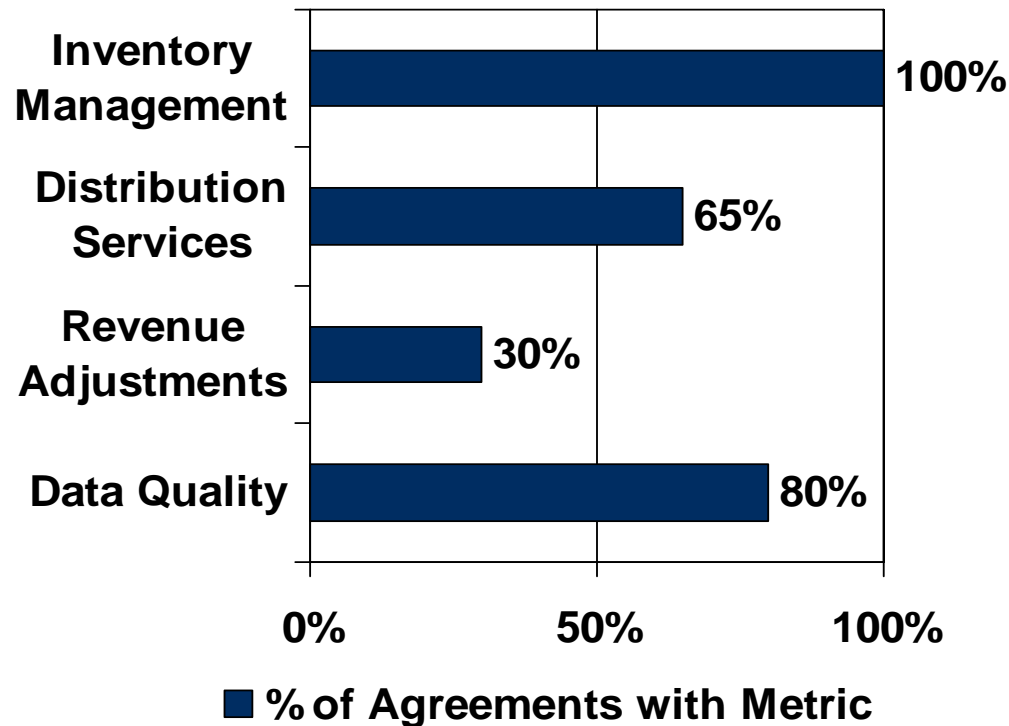
Regional Wholesaler
 National Wholesaler
 Pharmacy
 Patient

Typical Metrics in Channel Commerce

- Inventory & Demand Management
 - Overstocks, out-of-stocks, buying patterns, order variability, forecast accuracy
- Distribution Services
 - Order fulfillment, service fill rates, primary market use
- Revenue Adjustments
 - Deductions, chargebacks, rebates
- Data Quality
 - Frequency, timeliness, completeness, consistency

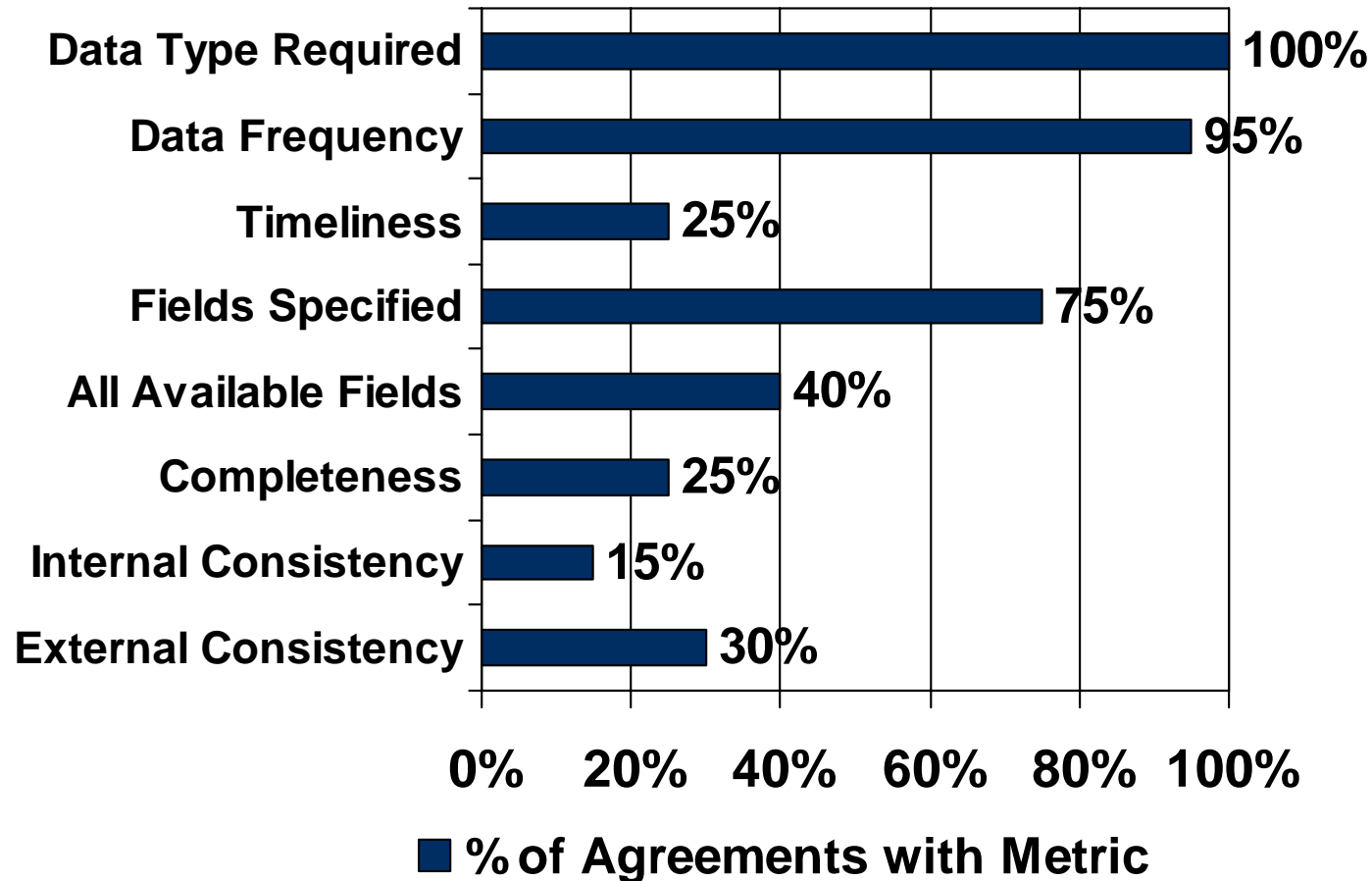
Performance Metric Survey

Performance Metrics



Data Quality Metrics Survey

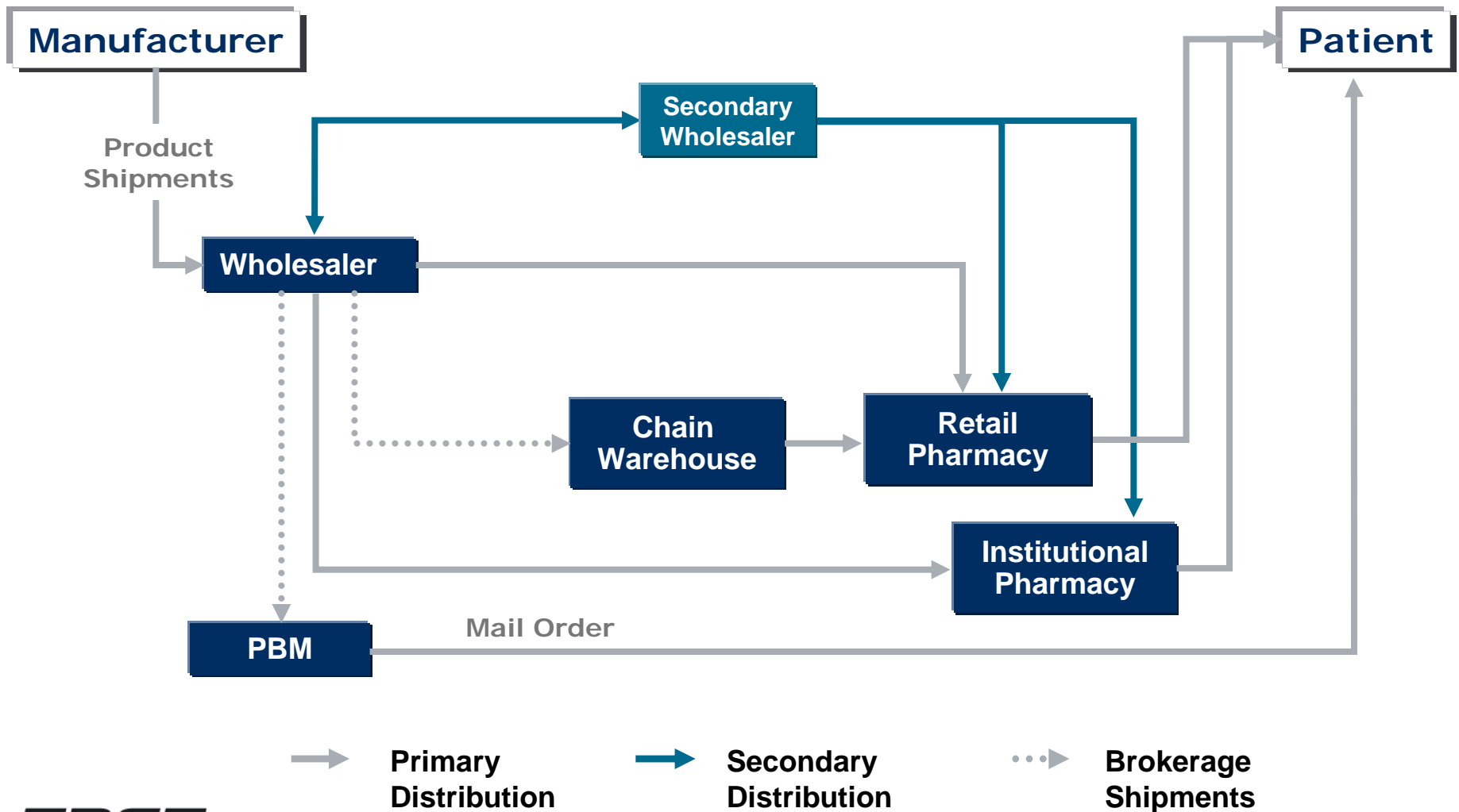
Specified Performance Metrics



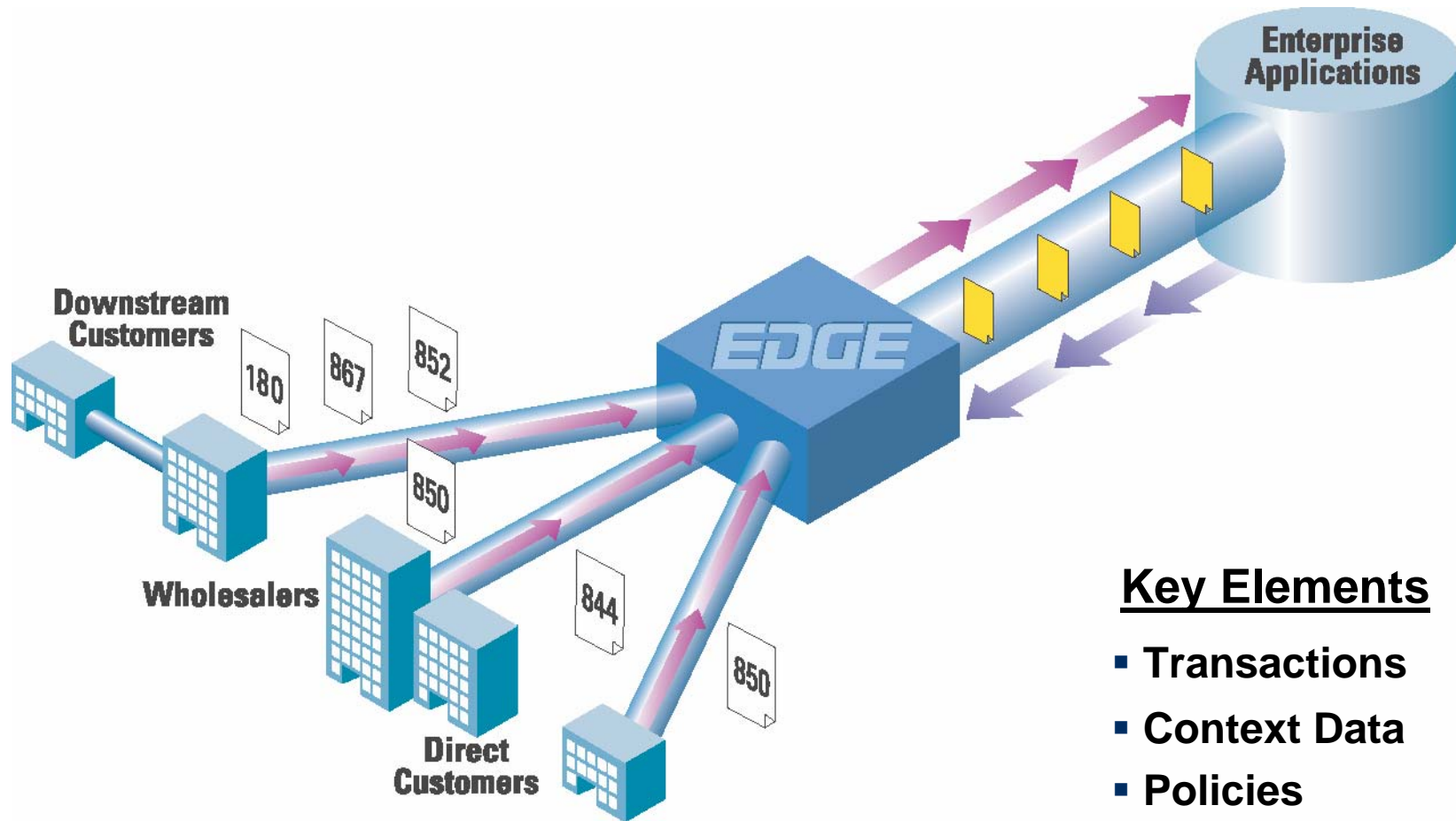
Evolution of Enterprise Technology

- Legacy enterprise systems, very limited data or analytics
- Current generation systems, moderate but inconsistent data, limited analytics
- Next-generation systems, extensive data, deep real-time analytics

The Pharma Distribution Channel: Complex Flows of Product, Money, Information



Channel Commerce Management Technology in the Enterprise



Key Elements

- Transactions
- Context Data
- Policies
- Corrective Actions
- Auditable Repository

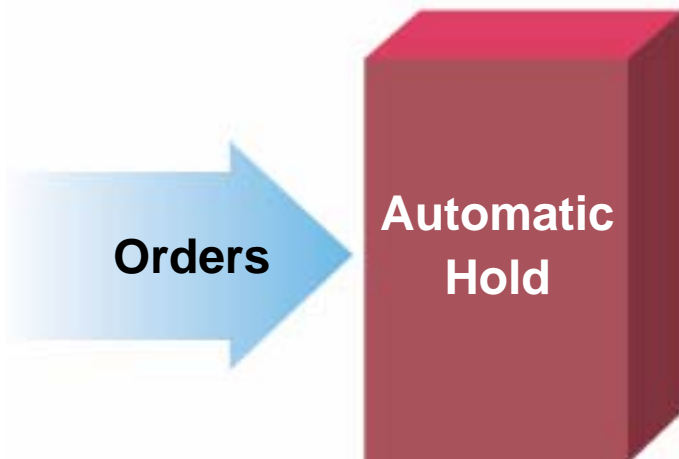
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Applying Technology: Managing Exceptions

Before

Manual or Legacy Systems

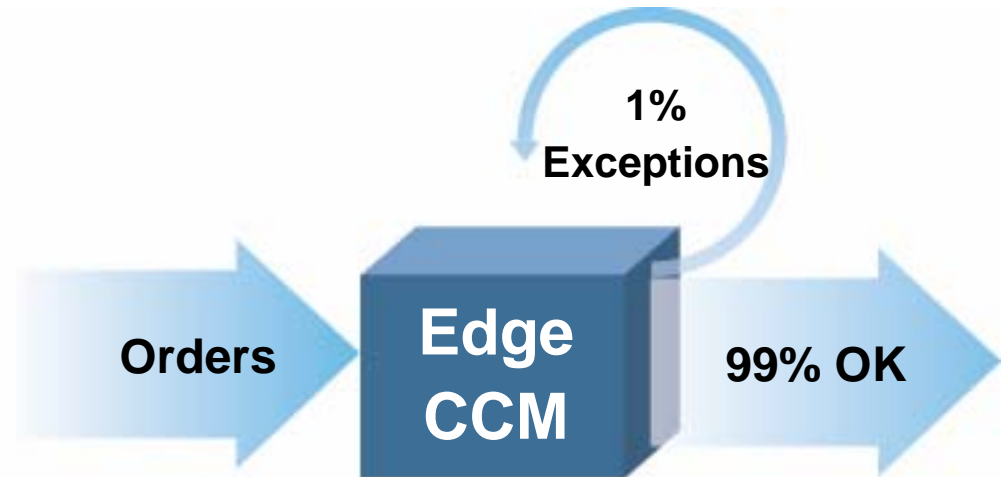


Challenges

- Process delays
- Ad hoc methods
- Inconsistent business results
- Compliance risk

After

Edge Solution



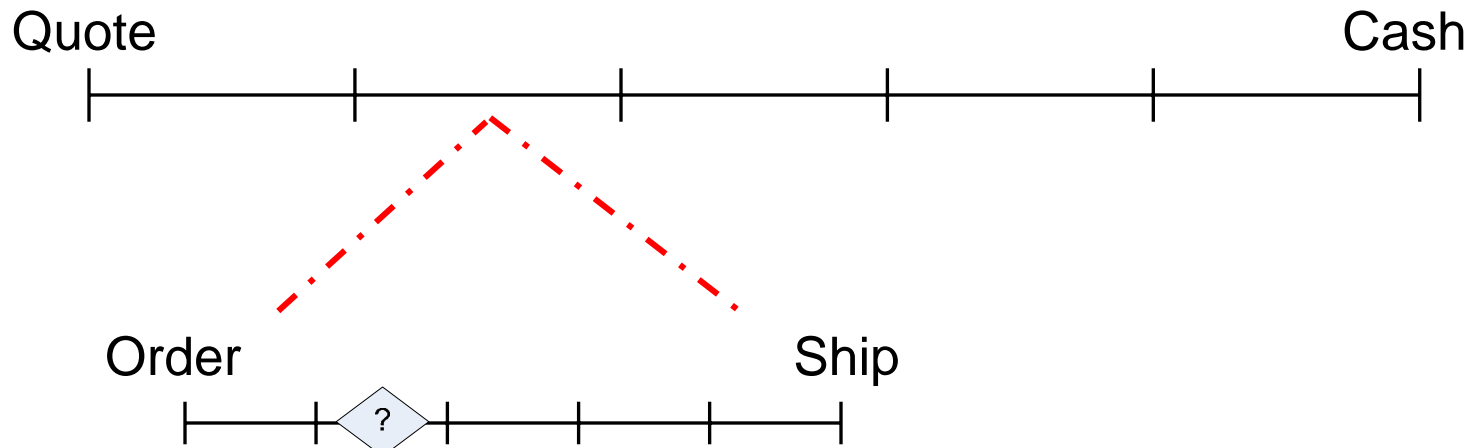
Benefits

- Accelerated fulfillment
- Consistent best-practice
- Predictable performance
- Comprehensive audit trail

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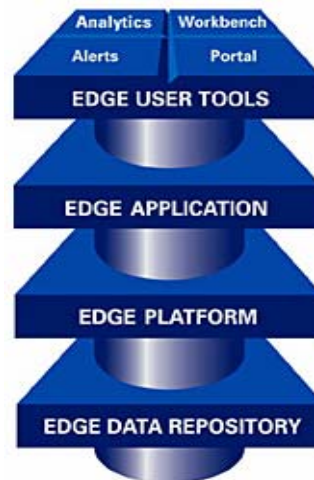
How it works: Policy Injection



R/3 SD

Policy Controls

- Regulatory Constraints
- Corporate Objectives
- Trade Agreements
- Market Dynamics



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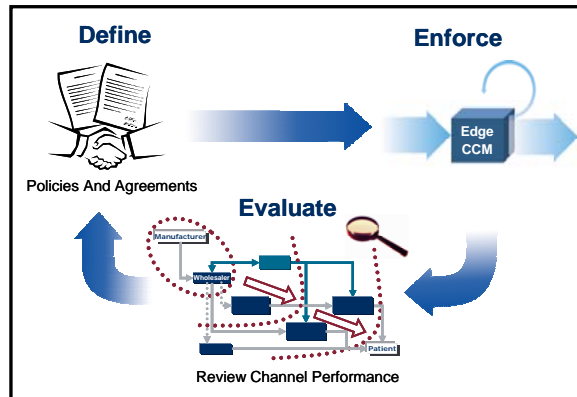
OCA

Order Review
And Approval

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Key Elements of Enterprise Technology

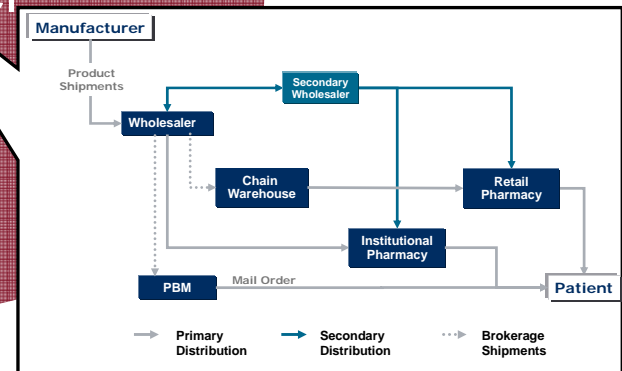


Enterprise Class Solution

Enterprise "Abilities"
 Reliability
 Scalability
 Transactionality
 Auditability
 Compliance

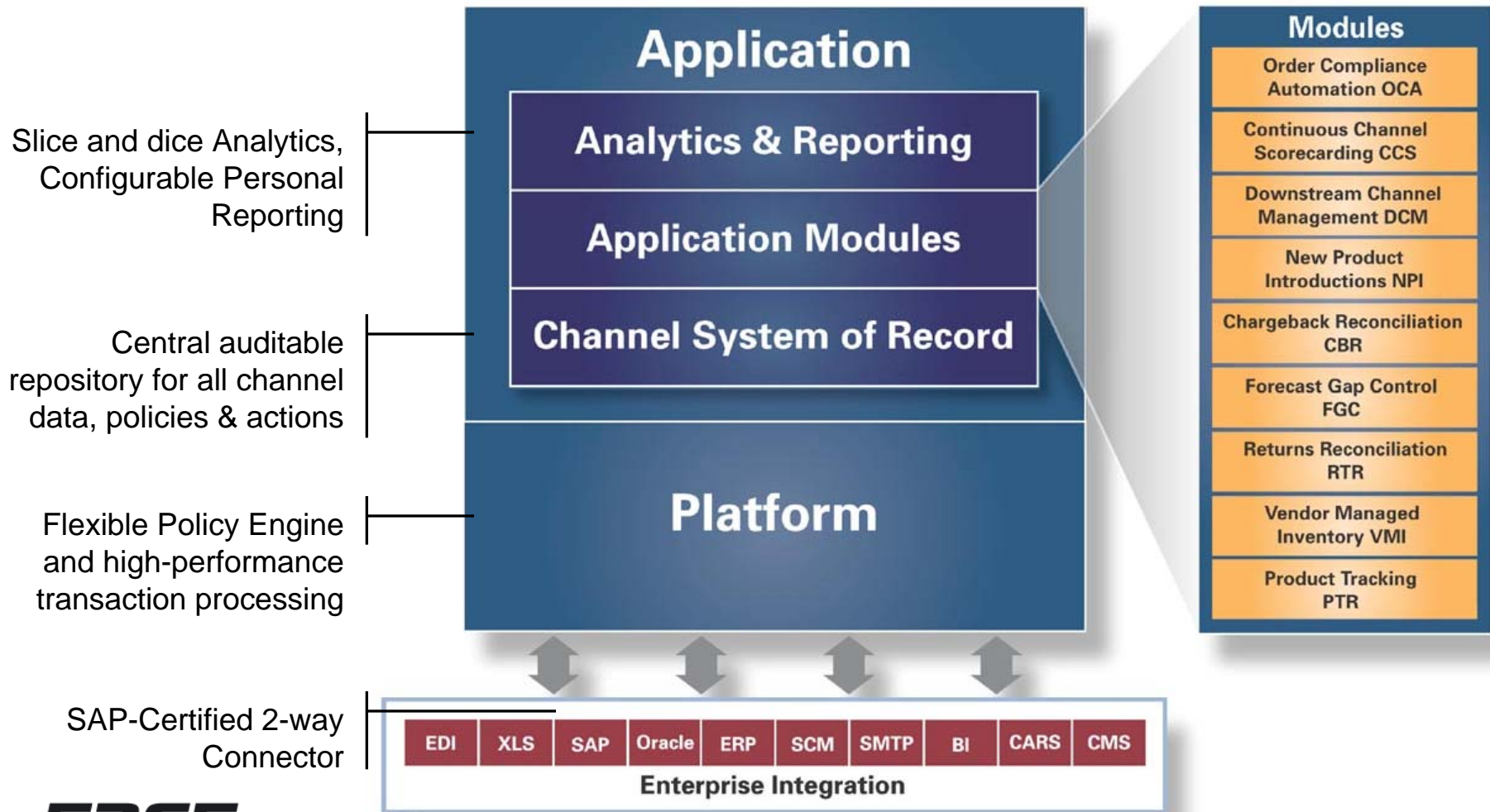
Policy Management Platform

Comprehensive Channel Model



Layers of Enterprise Technology

Available as On-Premise and Hosted Solutions
Edge CCM Enterprise



Summary: Technology Can Be Applied Effectively to Compliance & Risk Mgmt

Robust commercial operations mgmt requires transparency, accountability, control

and can enable improvements in:

Financial Performance

Regulatory Compliance

Market Integrity / Patient Safety

Thank you for your attention

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