

# DSCSA Compliance Exceptions: Orchestrating Exception Management from Issue Identification to Resolution

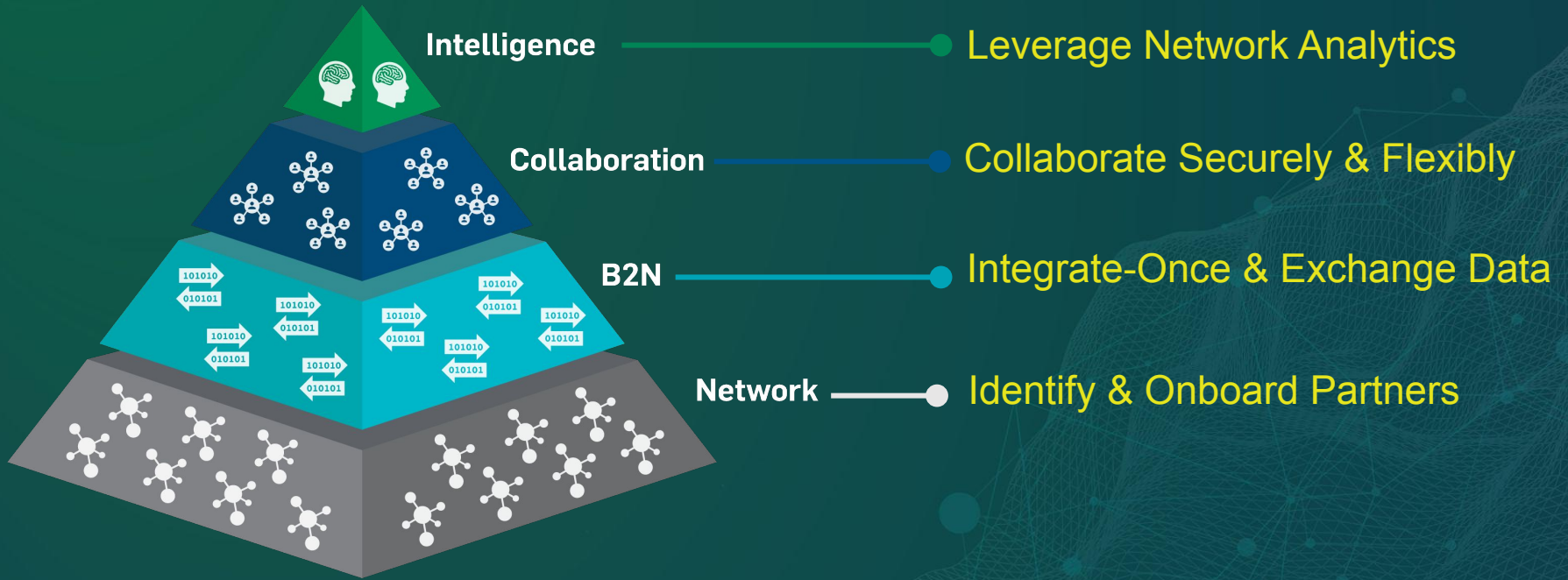
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Sr. Solution Consultant



# Track-and-Trace Experience Created the Formula for Digitalization

## Four Ingredients for E2E Supply Chain Digitalization



# The Challenge

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The November 2023 DSCSA regulations will cause a sharp increase in exceptions and inconsistencies which can disrupt the pharmaceutical supply chain.

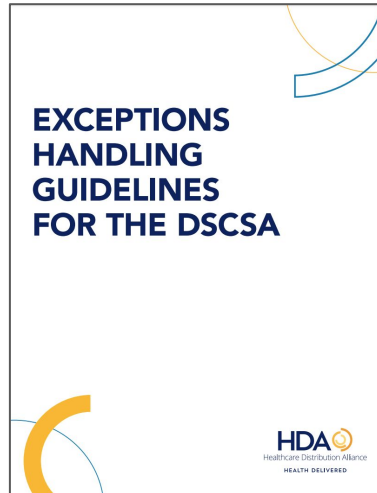


# DSCSA Requires TI/TS Data Exchange, Adding Complexity

Before product can be sold downstream, exceptions must be communicated and resolved with trade partners.

## HDA has identified 5 exception categories:

1. Data Issues
2. Product, No Data
3. Data, No Product
4. Packaging & Labeling
5. Unavailable for Distribution:  
Product Is Recalled, Suspect or  
Illegitimate



## Examples...

- Incorrectly formatted EPCIS
- Damaged case/label
- Product received, then shipment quantity changed or cancelled
- 2D barcode will not scan, is encoded incorrectly, or has incomplete elements
- Serial Number in HOLD status during pick/pack/ship due to recall, suspect, or illegitimate product

# DSCSA Exception Categories & Sub-Categories

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## Data Issues

- Non-matching GLN
- GTIN not found
- Incorrectly formatted EPCIS
- Data received/barcode data misalignment

## Damaged Product

- Damaged case/case label
- Damaged each (bar code or HRI)

## Product, No Data

- EPCIS sent but not received
- Product received, serial number not found, no PO or delivery number
- Product received, serial number not found, PO exists
- Product overage with valid PO
- Delivery to right company, wrong DC
- Delivery to wrong company
- Serial number not found due to aggregation or overage during pick/pack/ship

## Data, No Product

- Data sent but product not received (possibly due to shortage)
- Data received, then shipment quantity changed or cancelled
- Data received, shipment refused or undeliverable
- Data received, shipment lost or stolen

## Packaging

- Scan on receipt product/data mismatch due to batch labelling issue
- No HRI of serial number on label upon receipt
- Serialized shipping container code damaged or unusable
- Barcode will not scan, is encoded incorrectly or has incomplete elements
- No HRI serial number on label at pick/pack/ship

## Product Hold

- EPCIS events out of sequence, do not match product status
- Serial number in HOLD status during pick/pack/ship due to recall, suspect, or illegitimate product

# The Opportunity to Collaborate

## Solution: Supply Chain Work Management for Compliance Exceptions

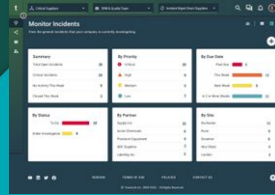
Leverage an easy to use, single, centralized location to collaborate and resolve issues quickly with all supply chain partners.



# Supply Chain Collaboration – Everyone Engaged

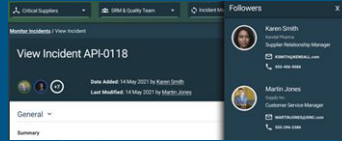
TraceLink's Supply Chain Work Management

Measure KPI Performance & Monitor Supply Chain Threats



Cross-Functional & Cross-Company Executives

Collaborate to Resolve Exceptions & Underlying Issues



Cross-Functional & Cross-Company Teams

Update and resend EPICS

Return Product

Receive at the Case Level

Reconcile overages or shortages

Data Issues

Damaged Product

Product, No Data

Data, No Product

Packaging

Product Hold

Report Deviation



All Employees



Non-matching GLN



GTIN not found



Incorrectly formatted EPICS



Barcode data misalignment



Damaged each



Damaged case



Customers



3PLs



Transportation



Distribution



Manufacturing



Co-Packers



Contract Manufacturers



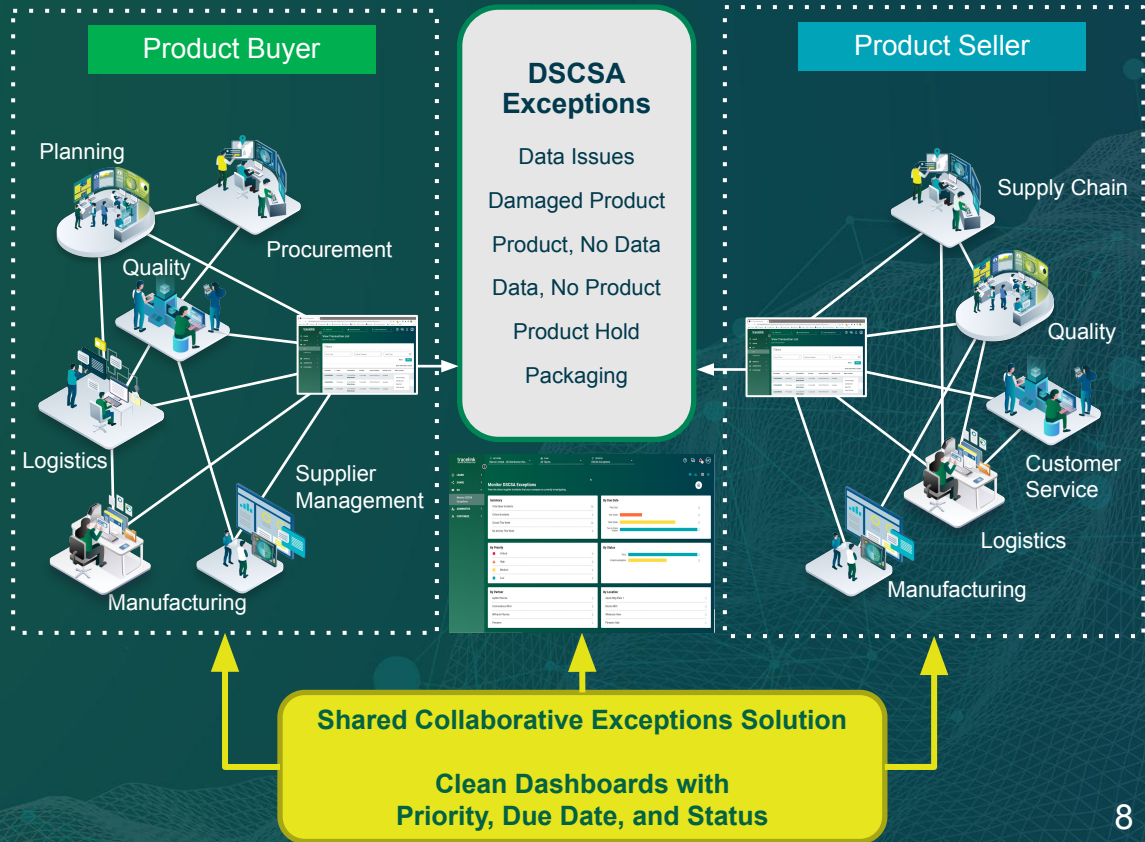
Material Manufacturers

# Supply Chain Work Management for Compliance Exceptions

Improve visibility and coordination in a shared digital platform

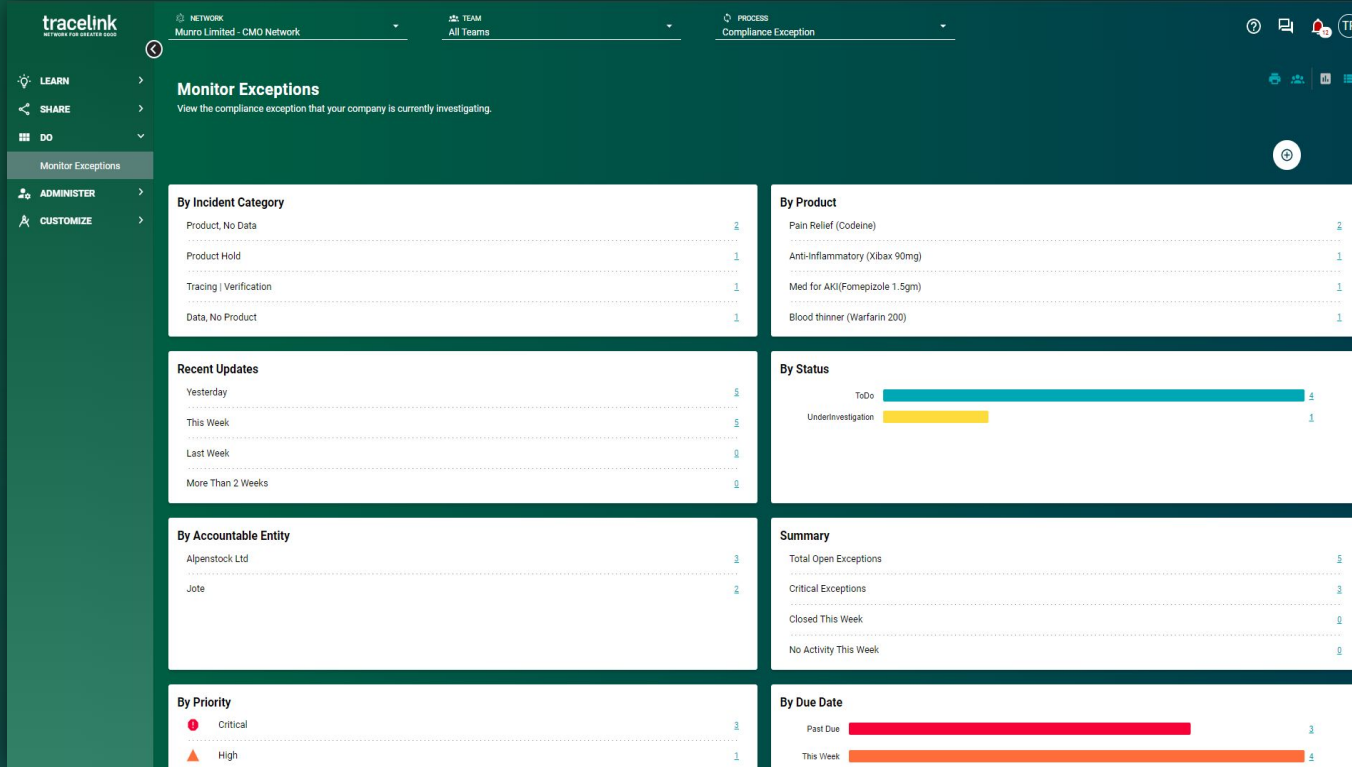
## Key Capabilities

- Manage exceptions beyond EPCIS file conformance
- Dashboards drive visibility to all issues, priority, risk status, due dates and partner performance
- Identify and assign to correct owner and team across departments
- Notifications for actions and approaching due dates
- In-context discussion trail and attached documents for complete context and visibility to entire team
- Root cause capture and linking to related incidents





Utilize real-time dashboards, providing users with visibility into priority, due date, and status, as well as reports and historical data to ensure prompt resolution.



# Leverage filter and search features in a tabular view to isolate and focus on specific exceptions using key attributes

The screenshot displays a web application interface for monitoring exceptions. At the top, there are navigation menus for NETWORK (Munro Limited - US Distribution Network), TEAM (All Teams), and PROCESS (Compliance Exception). The main heading is 'Monitor Exceptions' with a subtext: 'View the compliance exception that your company is currently investigating.'

The 'Filters' section includes three input fields: 'Keyword', 'Accountable Entity', and 'Status' (set to 'All'). There are 'RESET' and 'APPLY' buttons. Below this, there are two dropdown menus: 'Filter By' (set to 'Disposition Type') and 'Disposition Type' (set to 'Approve Release'). An 'ADD ANOTHER FILTER' button is also present.

The table below shows two exception records:

Priority	Exception ID	Incident Category	Summary	Status	Accountable Entity	Last Modified	Due Date	
●	<a href="#">USD-88</a>	Packaging	Case 3_SPI: Shipments received with damaged labels unable to scan at the destination.	UnderInvestigation	Franks Pharma	2023-10-17 by <a href="#">Terence Puryear</a>	2023-10-31 (12 days)	:
●	<a href="#">USD-87</a>	Data, No Product	Case 2_SPI: Shipments not 100% received at the destination as against the Data Available	ToDo	Franks Pharma	2023-10-17 by <a href="#">Dennis Munro</a>	2023-10-31 (12 days)	:

# Manage exceptions beyond EPCIS file conformance, identifying and assigning exceptions to proper owners and teams across departments.

**View Exception USD-88**

**TP JB +3**

Date Added: 2 OCT 2023 by Tereance Puryear  
Last Modified: 17 OCT 2023 by Tereance Puryear  
Following this compliance exception

Status: Under Investigation

### General

**Summary**  
Case 3\_SPI: Shipments received with damaged labels unable to scan at the destination.

**Description**  
Labelling issue, missing HRI on the package, damaged labels, unable to scan etc.

<b>Business Priority</b> Low	<b>Resolution Due Date</b> 10/31/2023
<b>Incident Category</b> Packaging	<b>Incident Sub-Category</b> 2D barcode will not scan, is encoded incorrectly or has incomplete elements
<b>Responsible Party at Reporter</b> Tereance Puryear	<b>Reporter Company</b> MUNRO LTD, (GLN) 0495010100015
<b>Business Unit</b> Supply Chain	<b>Date Submitted</b> 10/17/2023

**Current Assignees at Reporter**  
Jag Brijesh

# Update and review, in-context, comments and attachments for complete understanding and visibility to the entire team.

**NETWORK**  
Munro Limited - US Distribution Network

**TEAM**  
All Teams

**PROCESS**  
Compliance Exception

TP

SUBMIT COMMENT

### Comments and Attachments

Added By	Internal Only	Comments	Attachments
Anurag Nagpal on Mon Sep 11 2023 at 2:02 PM	No	This incident is classified as 'Data, No Product'. Should the classification be changed to 'Product, No Data'. The description of the incident too states 'received the shipment 369287709143 but do not have the shipment message'. Have also checked Shipment 369287709143, and we see that 111 serial numbers were shipped - 100 EA, 10 Cases, 1 Pallet.	
Anurag Nagpal on Mon Sep 11 2023 at 1:49 PM	No	The incident is categorized as 'Data, No Product'. Should the correct classification be 'Product, No Data' - as the description states 'received the shipment 369287709143 but do not have the shipment message'.	
Anurag Nagpal on Mon Sep 11 2023 at 1:49 PM	No	The incident is categorized as 'Data, No Product'. Should the correct classification be 'Product, No Data' - as the description states 'received the shipment 369287709143 but do not have the shipment message'.	
Michelle Franks on Fri Aug 11 2023 at 6:42 AM	No		

# Supply Chain Work Management is Easy to Adopt and Use

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- Cloud Software
- No Integrations Required
- Pre-Built Solutions
- Low-Code / No-Code Configuration

Easy to Start



- Quickly Invite New Users
- All Partner Onboarding by TraceLink
- No Costs for Partners
- Single Network Login

Easy to Network



- Intuitive User Experience
- Mobile Responsive
- Proactive Notifications
- Time Savings

Easy to Use

# Why TraceLink?

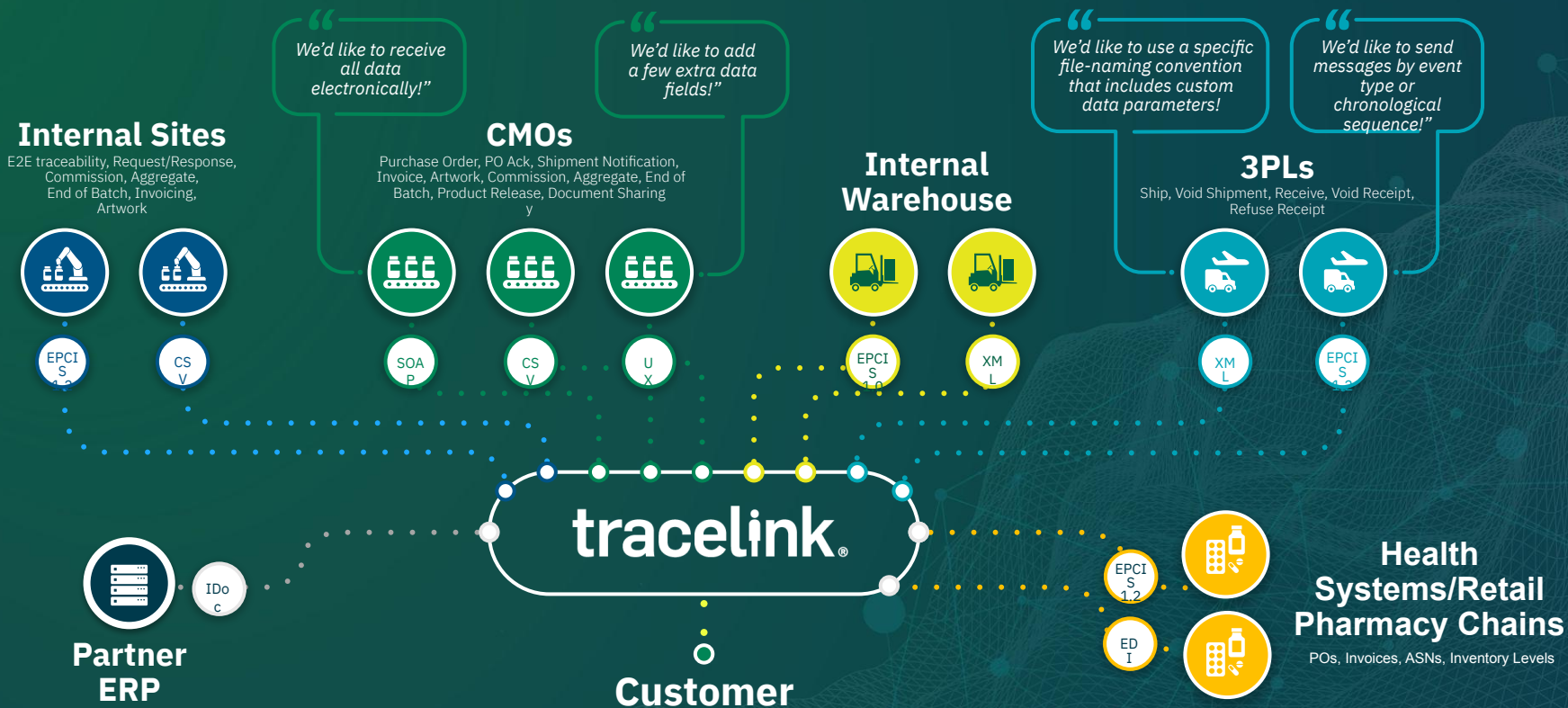
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Because the TraceLink Opus digital network platform delivers the critical capabilities needed for digital supply chain transformation.



# Integrate Once, Interoperate with Everyone™ in any format

\*Integration is not required to get started today



# Call to Action

- Share with your colleagues responsible for the managing DSCSA Compliance Exceptions.
- Schedule a meeting with your TraceLink Account Executive to discover how SCWM can improve your management of your exceptions.
- Stop by the Product and Solution Fair to see **SCWM** live.



# Thank You





































