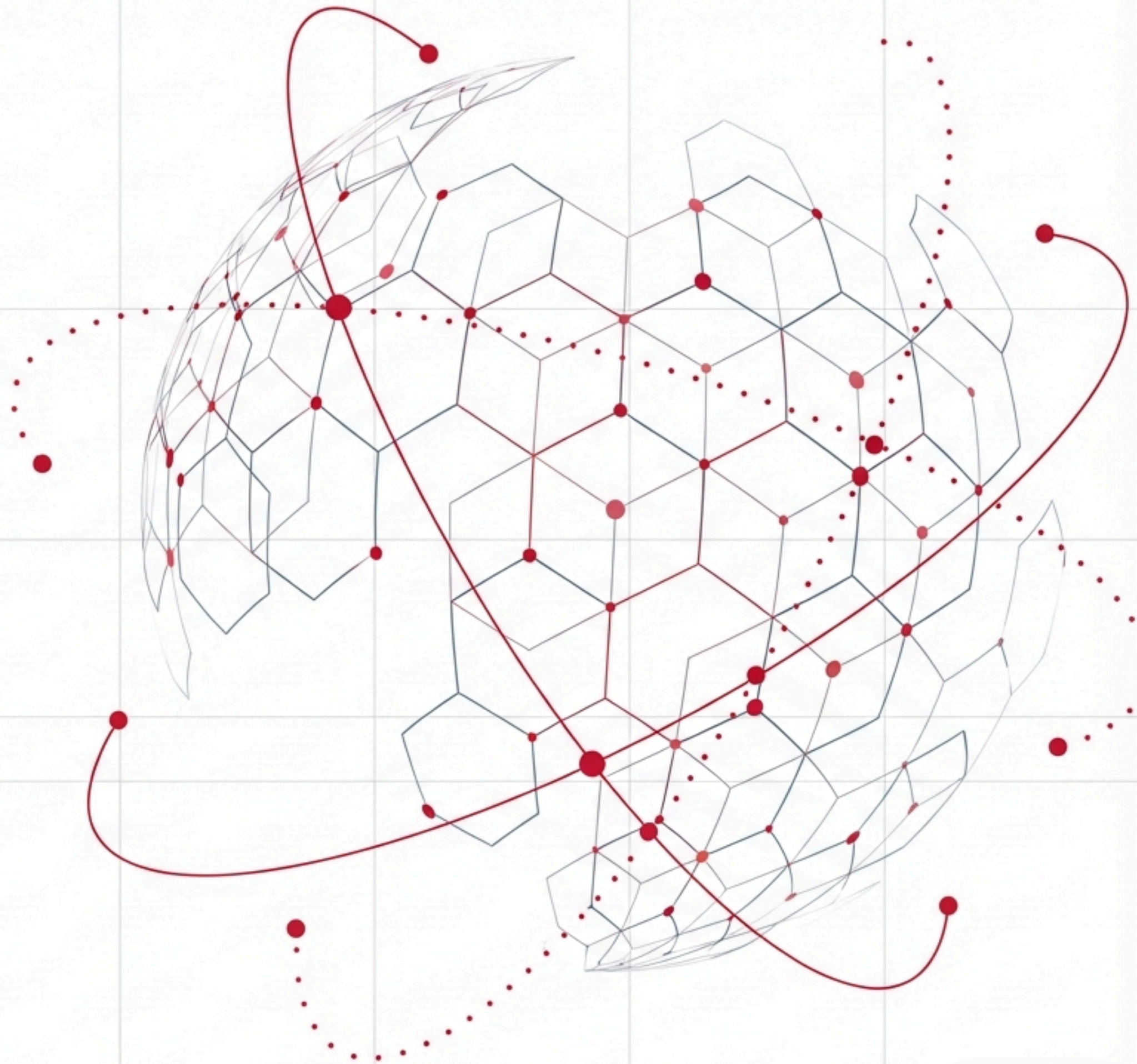




# Global Pharma Serialization: 2026 Updates

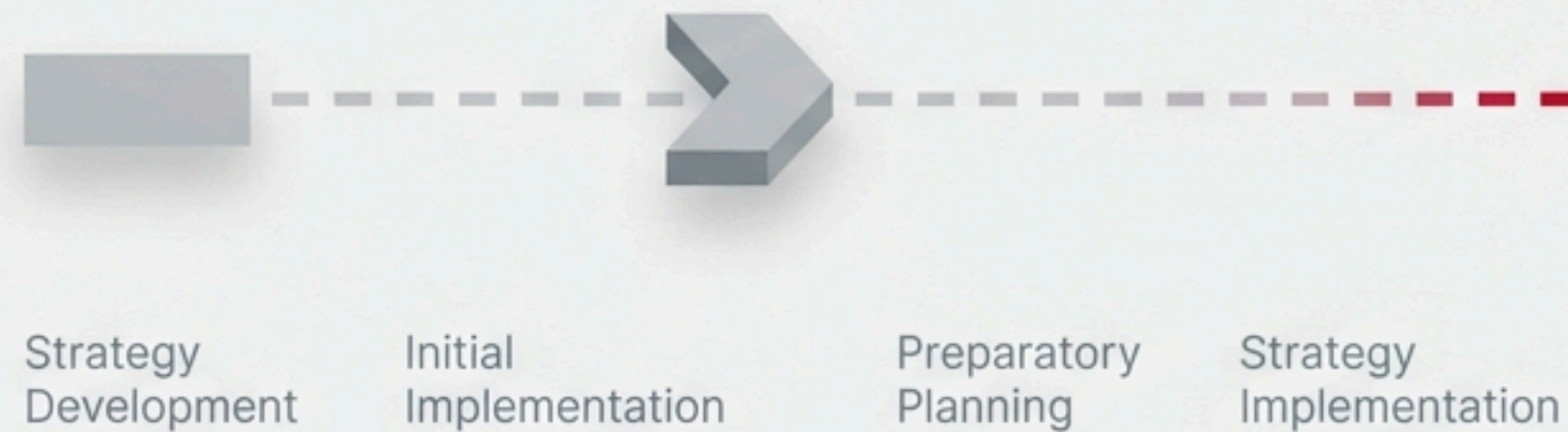
Navigating the Year of Enforcement

Driving pharma forward  
February 2026  
Presented by Nubinno



# The 2026 Theme: The Year of Enforcement

## 2024-2025: Planning & Transition



## 2026: The Year of Enforcement



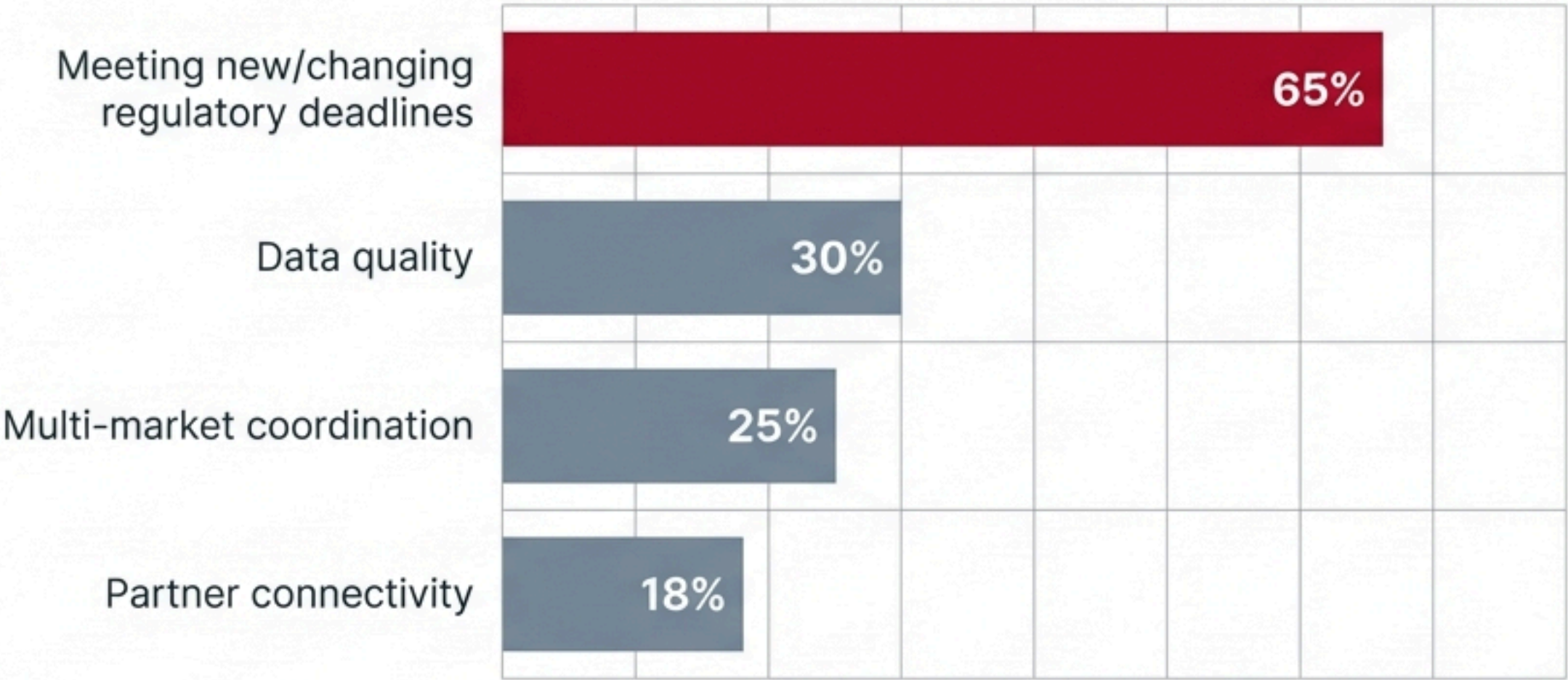
The Shift: Markets are moving from transition periods to mandatory compliance.

The Reality: Grace periods are ending in the US, Jordan, and Ethiopia. The era of “getting ready” is over.

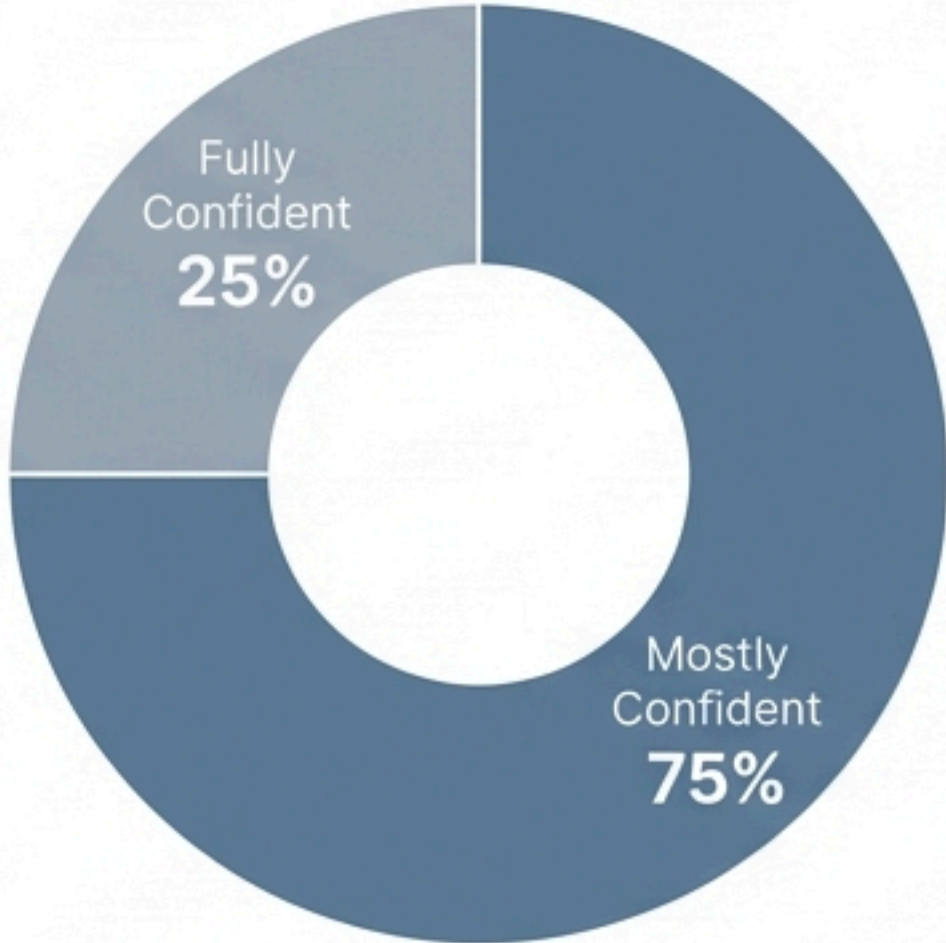
**“Many markets are moving from planning to full compliance.”**

# Industry Pulse: Risks vs. Readiness

## Top Risk Factor



## Data Quality Confidence



Insight: While organizations feel secure in their data quality, anxiety stems from the sheer volume of **regulatory deadlines** landing in 2026.

# USA (DSCSA): The Final Compliance Milestone

---

**NOV 27, 2026**



## **Target Group:**

Small Dispensers ( $\leq 25$  staff)

## **Deadline:**

November 27, 2026

## **Mandatory Requirements:**

- Electronic EPCIS (No paper/PDFs)
- Global Location Number (GLN) required for receipt
- 2D Barcode Scanning & Verification
- 6-Year Data Retention

# US Data Integrity & Future Standards

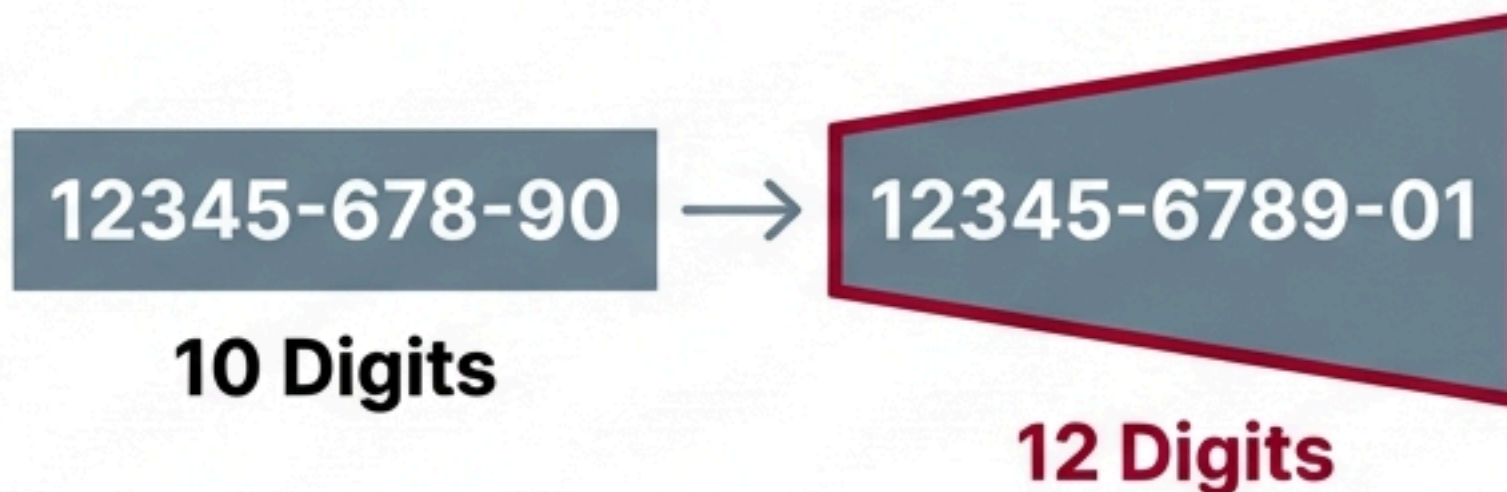
## The Zero-Error Expectation



Exception Handling:  
The 72-Hour Rule.  
Exceptions (Data No  
Product, Product No  
Data) must be  
resolved within 3  
days.

**Target Error Rate:  
Business reality  
demands 0%.**

## NDC Format Change



Proposal: FDA shift from 10-digit to 12-digit NDC.

Timeline: 5-year window post-final rule.

- **Action: Assess vendor capability now.**

# Italy: The Stabilization Period (2025–2027)



## Current Status

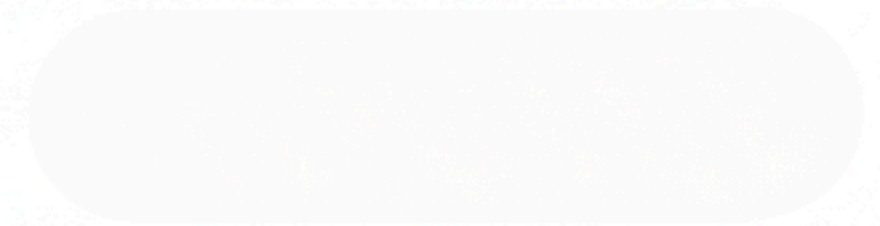
NMVO Italia established.  
NMVS not fully operational.

## Pilot Phase 2 (Feb – April 2026)

**Scope:** Sellable products & Carta Valori (Allegato B).  
**Restriction:** Participation by invitation only.

**! Mandatory Action:** Onboarding & fee payment is required **NOW**, regardless of stabilization.

# Egypt: Navigating Regulatory Ambiguity



## Deadlines

### Official Deadlines

- ✓ **Feb 1, 2026:** Imported medicines
- ✓ **Aug 1, 2026:** Locally manufactured products



Local Partner

## Infrastructure/System Readiness

### The Reality & Fix

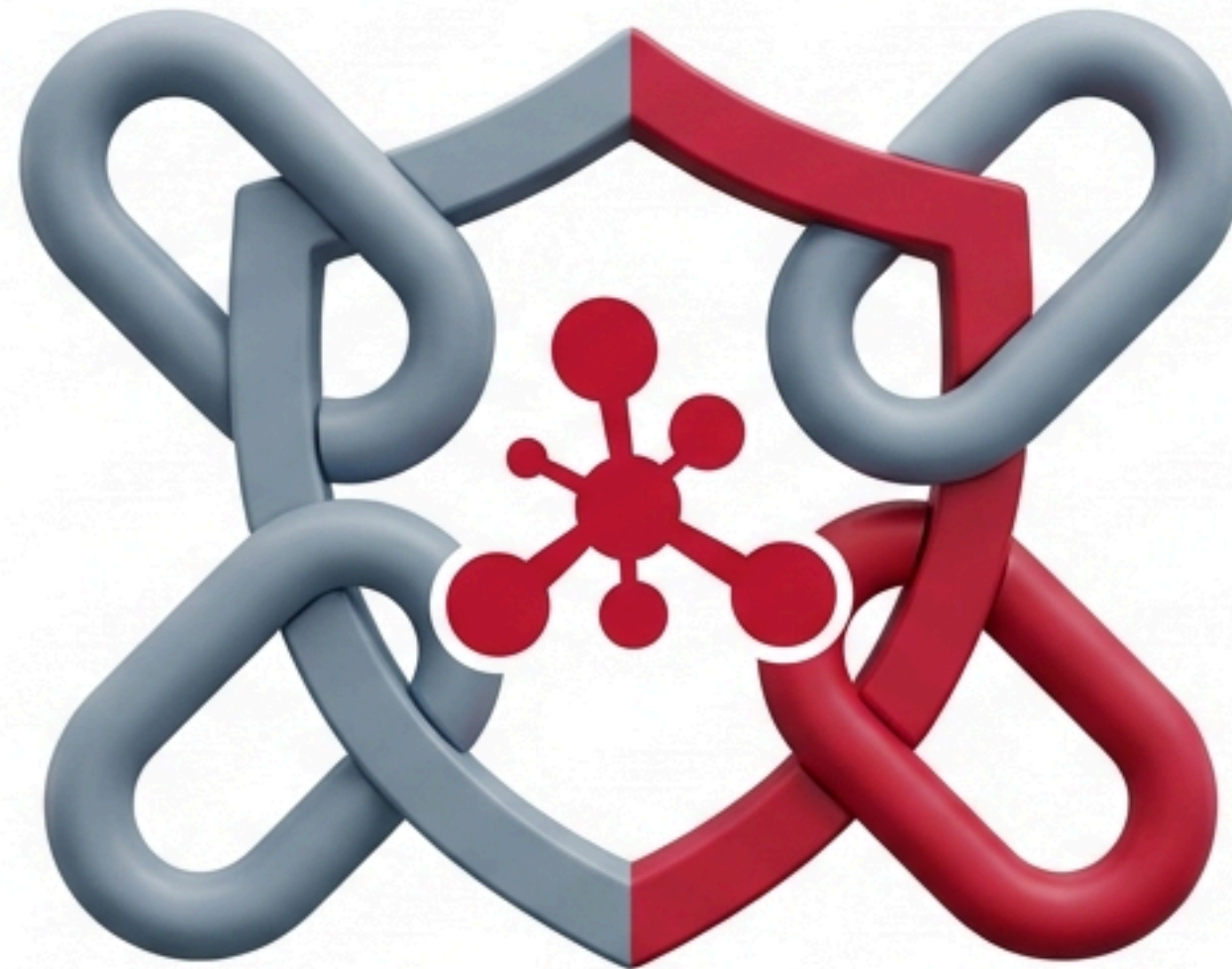
- ✓ **Challenge:** Pharma Data Hub not fully ready. Transparency is low.
- ✓ **Strategic Workaround:** Rely on local distributors to upload data and handle reporting.
- ✓ **Monitor:** [edaegypt.gov.eg](http://edaegypt.gov.eg) for updates.

# Ethiopia: A Strict, Blockchain-Based Approach

System: **EFDA-MVC Traceability Hub** (Blockchain)

**CRITICAL:**

eRIS approval is mandatory.  
No eRIS = No Traceability Hub access.



**Deadlines:**

**June 26, 2026:** Full traceability reporting.

**Dec 1, 2026:** Aggregation reporting.

**⚠** Authority is issuing 15-day registration ultimatums under threat of fines.

# Uzbekistan: Technical Evolution to xTrace 2.0



- **Dynamic Tokens:** Must renew every 30 days.
- **Credentials:** New username, password, and API keys required.
- **IDs:** Business Place ID required for each site.
- **Coding Standard:** Serial numbers must start with '7' (Prefix 'U' invalid from Dec 1, 2025).

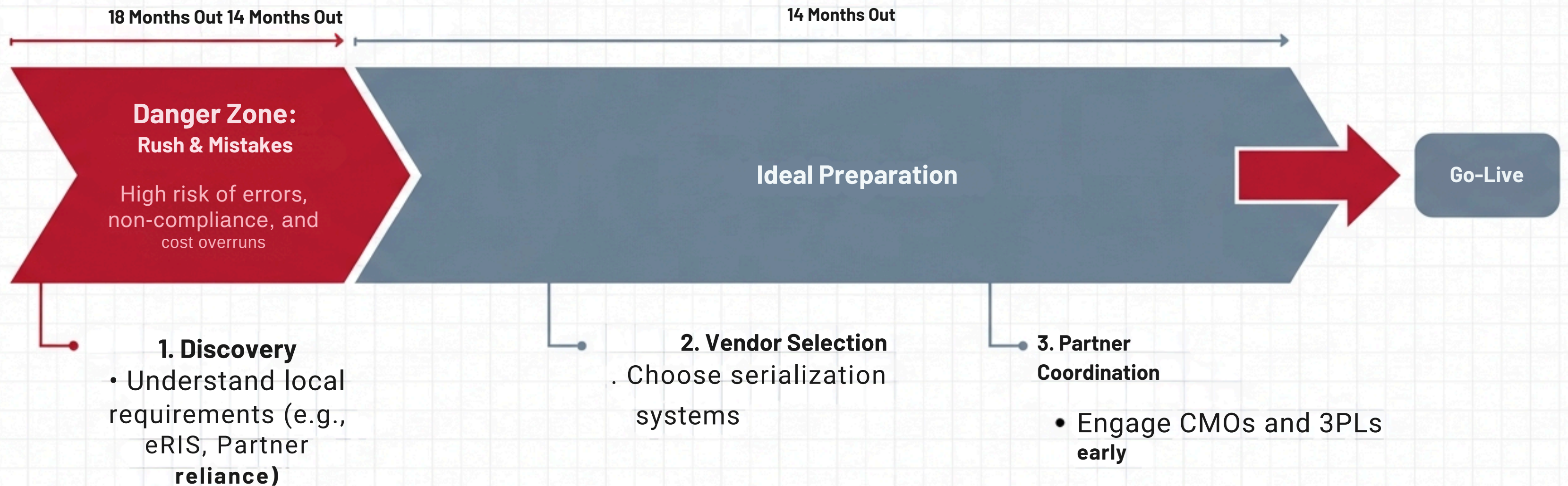
# Global Roundup: 2026-2027 Watchlist

03/09/2025 11:11



- **Jordan** (Jan 1, 2026)  
Verification focus, no central reporting.
- **Rwanda** (Aug 2026)  
Phase 2. Secondary packaging must include 2D DataMatrix.
- **South Africa**  
Phased roadmap (Batch → Unit → Logistics). Guidelines published.
- **Algeria**  
Mandatory 2D DataMatrix from 2027. Importer reporting obligation.
- **Azerbaijan**  
New regulations expected March 2026.

# Strategic Timeline: The Road to Compliance



# Expert Insights & Operational Tactics



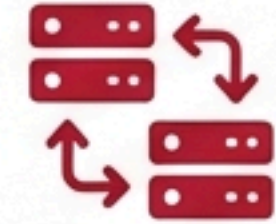
## Egypt Blockers

- **Problem:** Pharma Data Hub delays.
- **Tactic:** Use **local distributors** to register and report on your behalf.



## US Data Quality

- **Problem:** 'Acceptable' error rates.
- **Reality:** Partners want **Zero Errors**.
- **Tactic:** Automate exception handling for **72h resolution**.



## Integration

- **Trend:** Automated ERP-to-ERP data exchange to **eliminate manual entry errors**.

# Summary: The 2026 Imperatives

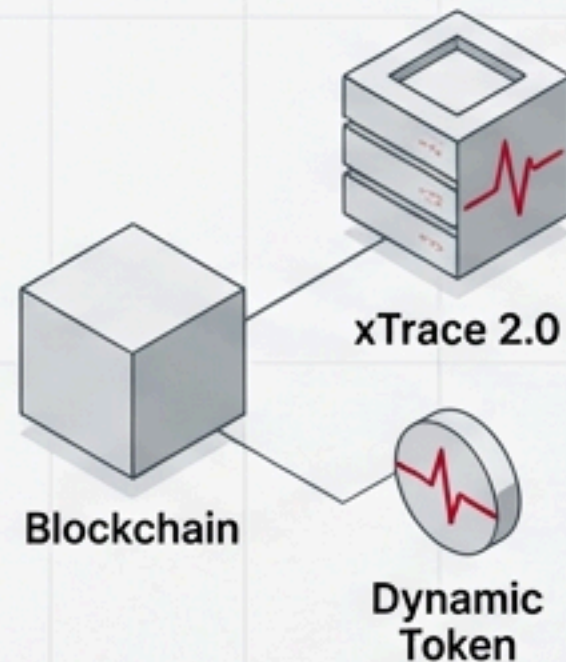
## 1 Enforcement is Here

Grace periods are ending in US, Ethiopia, and Jordan.  
**Compliance is mandatory.**



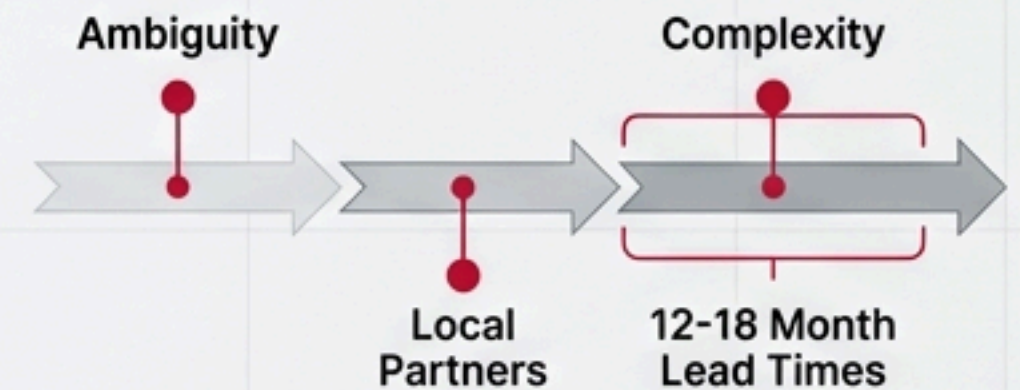
## 2 Technology is Evolving

From Blockchain hubs to xTrace 2.0 and Dynamic Tokens.

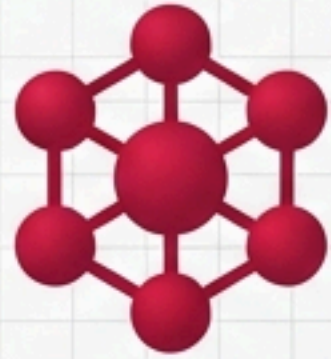


## 3 Strategy is Critical

Manage ambiguity with **local partners**. Manage complexity with **12-18 month lead times**.



# Stay Connected



Check the Compliance Map  
on [nubinno.com](https://nubinno.com)

Follow Nubinno on LinkedIn  
for real-time updates

## Q&A

Session Open  
for Questions