

BRAZIL COMPLIANCE

A step-by-step approach to serialization

Companies that manufacture and distribute medicines in Brazil are required to serialize every salable unit as part of the government's national track and trace regulations. Starting a serialization program from scratch takes time, planning, and resources to meet tight ANVISA milestones ahead of the April 2022 deadline.



1

ASSESS

Determine your requirements, products, and timelines

What role do you play in the Brazil supply chain? What products are in your portfolio, and what do their production cycles look like? Work backwards from the 2022 deadline to map out your product serialization timeline.

20-24 months before deadline



DID YOU KNOW?

TraceLink has helped more than **700 companies around the world** meet U.S. and EU serialization requirements.



The 4 types of supply chain events

- Activation (Manufacturers and importers only)**
License holder communicates the introduction of a medicine into Brazil's pharmaceutical supply chain.
- Shipping**
Company sends one or more packages of a medicine to a location within the supply chain.
- Receiving**
Company within the supply chain takes possession of one or more packages of a medicine.
- Termination**
Company, pharmacy, or hospital dispenses the product to a patient or destroys the product. Also includes the loss or theft of a product.

2

COLLABORATE

Survey your trade partners and assemble your team



What are your internal and external processes and systems? Which trade partners and internal departments will be impacted by serialization? Assemble the key stakeholders and understand their unique requirements.

What are serialization and aggregation?

Brazil law requires companies to apply a unique identifier (IUM) to each commercial unit of medication (serialization) and a serial shipping container code (SSCC) to packages that contain multiple individual serialized units (aggregation).



Brazil IUM 2D barcode



SSCC linear barcode

3

SELECT

Choose a primary serialization solution partner and supporting vendors

Who will provide expert guidance on your mission-critical serialization infrastructure, and what supporting systems will you need? Evaluate the best options before you decide on vendors and a strategic partner.



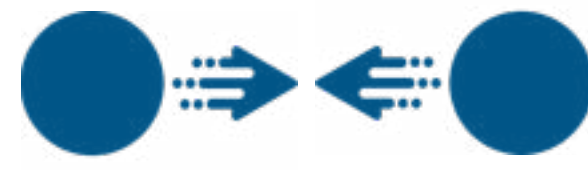
Serialization affects all of your partners and customers



4

Draft your "horizontal integration" plan

How will you exchange serialized product data with your partners and customers? What business and warehouse systems need to exchange data with your serialization solution? What supply chain events and transactions need to be reported to the government or communicated to your trade partners?



16 months before deadline

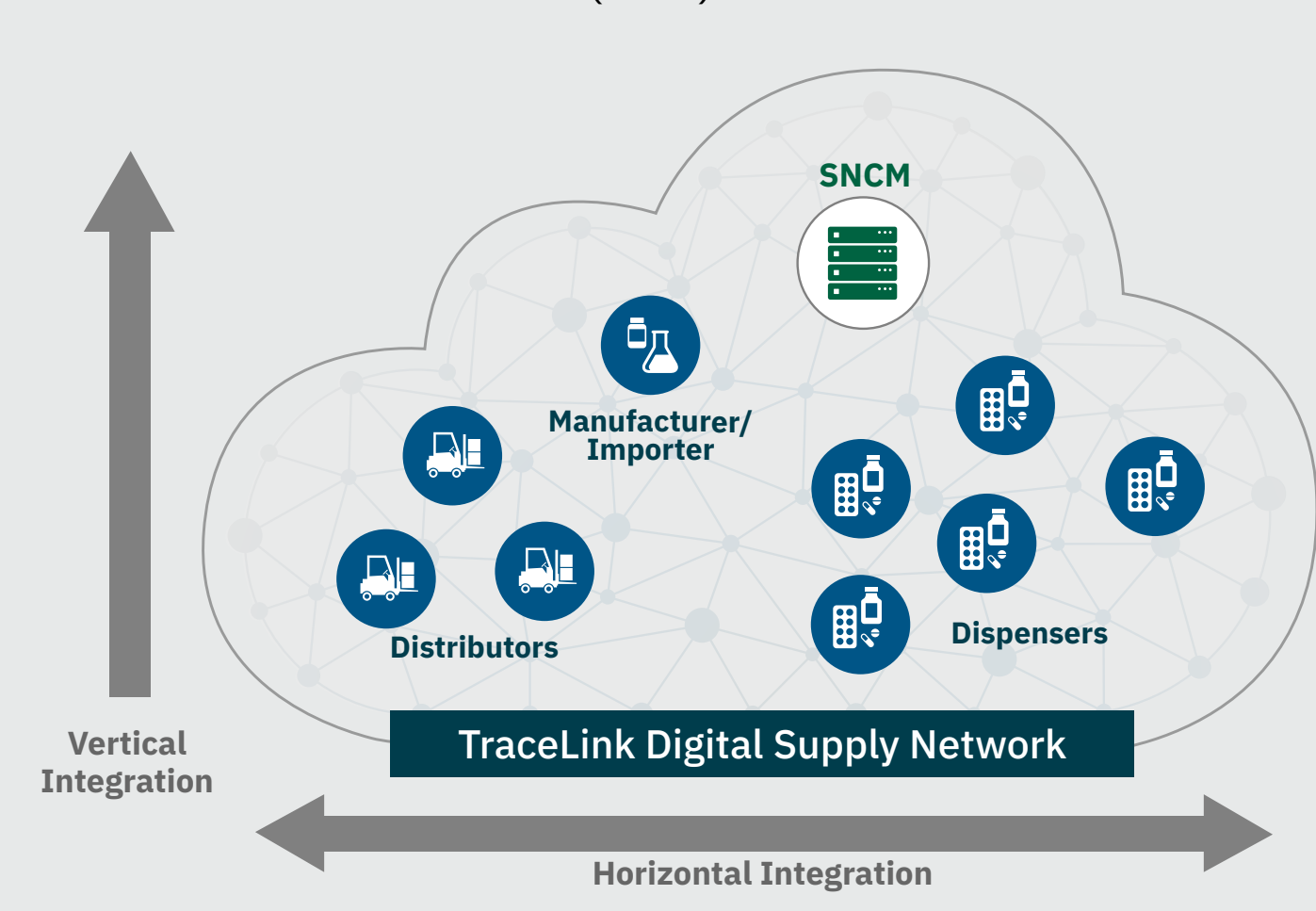
DID YOU KNOW?

There are more than **280,000 trading partners** on TraceLink's global digital supply network.



Data exchange across the supply chain

TraceLink's digital supply network eliminates the need to build and maintain individual point-to-point connections and simplifies both horizontal and vertical integration through a single login to a cloud-based software-as-a-service (SaaS) solution.



5

EVALUATE

Score your progress

Review your overall readiness at regular intervals to identify any gaps, look for opportunities to improve or optimize processes, and plan for the next milestone.

ARE YOU READY?

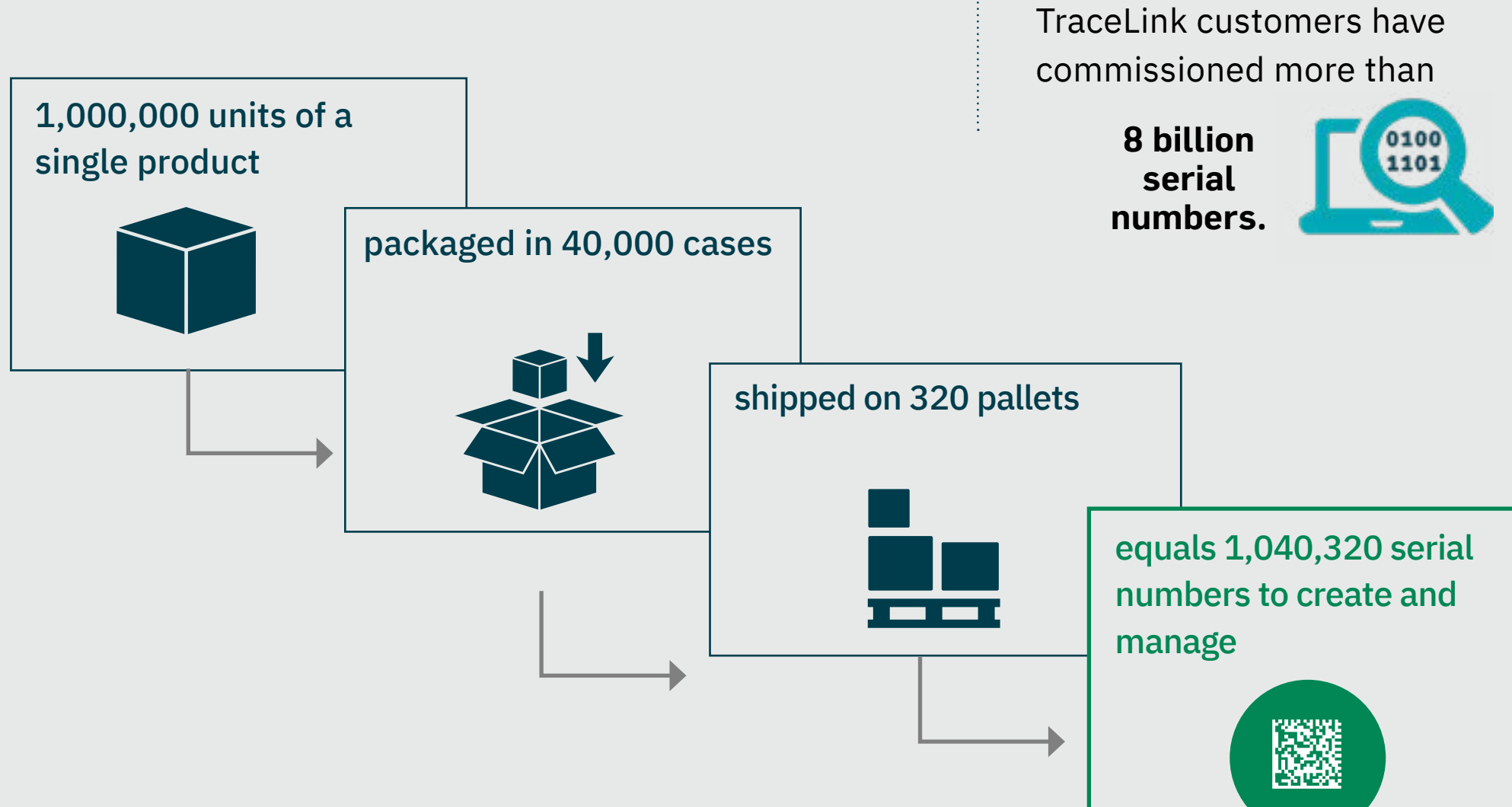
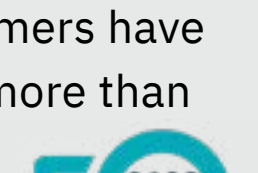
- Requirements defined
- Team assembled
- Business processes revised
- Partners on-boarded
- Aggregation plan in place
- Solution selected

Serialization numbers add up quickly

Remember that you need to apply serial numbers to every unit, case, and pallet. Every year, multiple products and multiple shipments will generate massive amounts of serial numbers to manage, track, share, and report.

DID YOU KNOW?

TraceLink customers have commissioned more than **8 billion serial numbers.**



12 months before deadline

6

Assess and iterate

How will you conduct a test run of your serialization solution across all product lines and SKUs? And how will you test your ability to exchange data with contract manufacturers, logistics providers, and trade partners?



7

EXECUTE

Begin producing serialized product

Based on demand, seasonality, shelf life, and other factors, which products will you serialize first? Finalize your production plan and begin serializing.



1 month before deadline

8

DELIVER

Congratulations!

You're on the path to meeting the ANVISA deadline. Start to outline your operational strategy for updating and validating your software to meet changing regulations, training staff, and leveraging serialized data to create new business value.



CONTACT US

What will your business look like in a serialized world? TraceLink has been an industry leader in Brazil track and trace requirements since 2013. Learn more about TraceLink's integrated compliance and serialization solution for Brazil.