Rx-360 Town Hall Meeting
April 16, 2020

Eric Marshall
Executive Director,
Partnership for DSCSA Governance

Town Hall Format

- This Town Hall is being recorded so Rx-360 can post on our website as an industry resource.

- During the Town Hall questions can be sent in via the Chat icon located on your screen or by emailing Brittany Doody at bdoody@rx-360.org

- When you do send in question, please provide your name and organization. There will be a question reminder throughout today's Town Hall

- All Slides from today's Town Hall will be available via the Rx-360 Website or upon request

DSCSA Basics

- **Drug Supply Chain Security Act of 2013 (DSCSA)**, 21 U.S.C. 360eee, *et seq*.
  - A 50-state state-by-state system risked leaving weak links, conflicting rules, or unnecessary burdens when the system relies on one or more state requirements.

- Supply Chain = Downstream Distribution Chain

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DSCSA Basics

1. Authorized Trading Partner (ATP) and Licensure Requirements
2. Suspect and Illegitimate Product Requirements
3. Verification Requirements
4. Product Tracing
   a. Lot Tracing
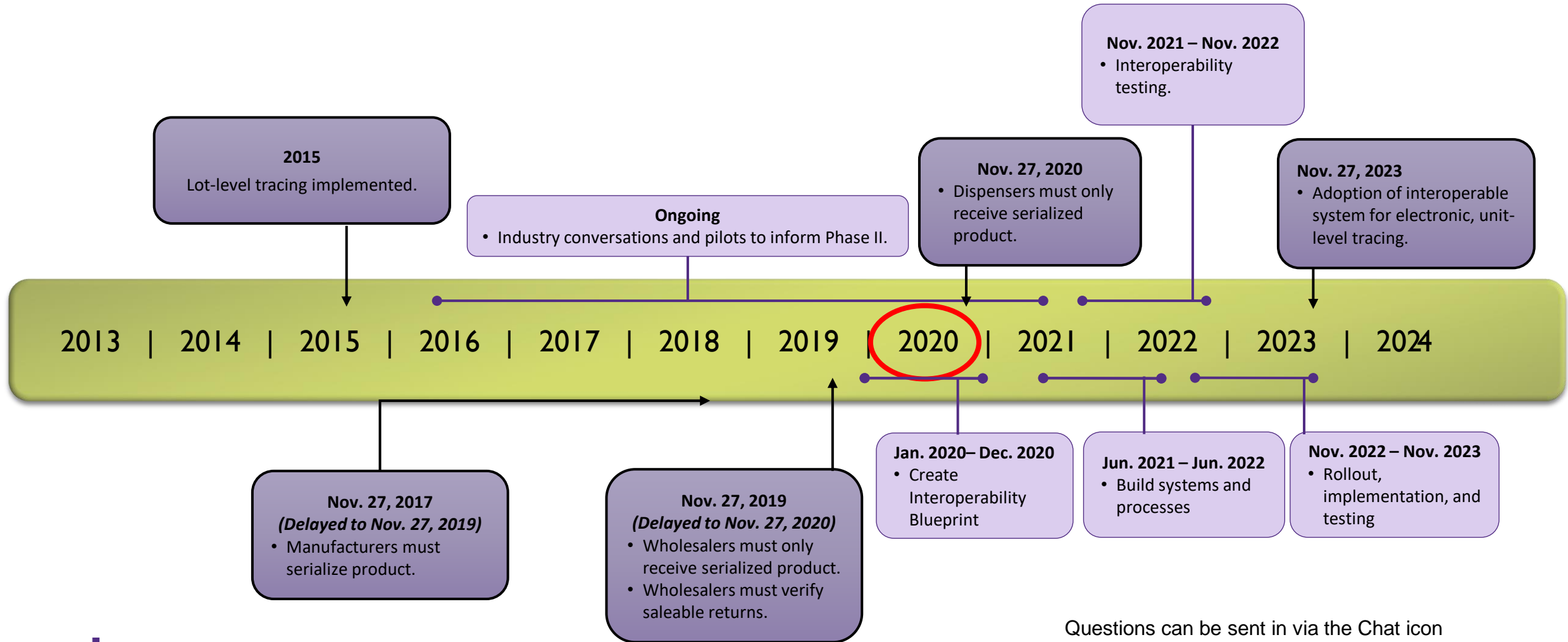   b. Unit Tracing

DSCSA Basics

Who is covered?

1. Manufacturers
2. Repackagers
3. Wholesale Distributors
4. Third-Party Logistics Providers
5. Dispensers

What is covered?

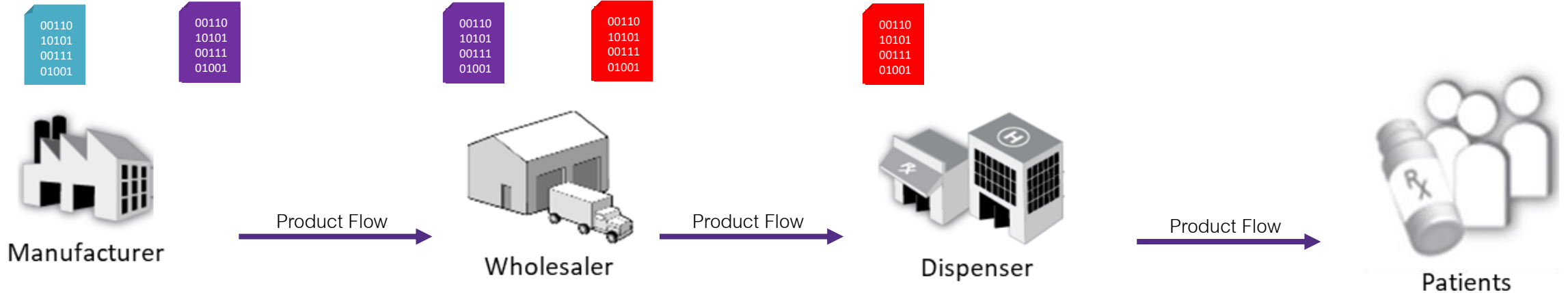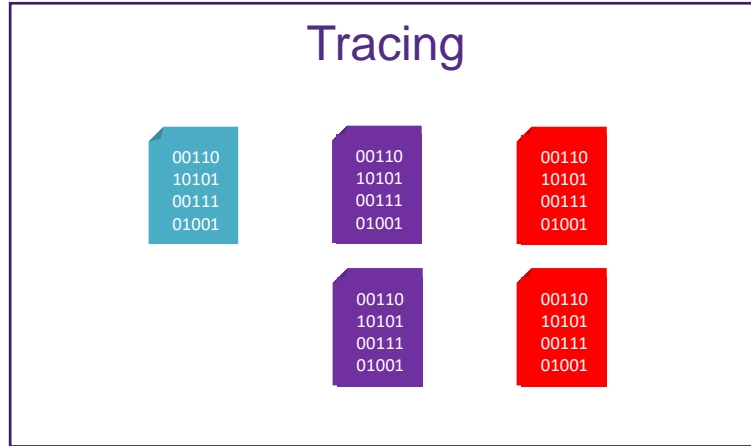Every <u>transaction</u> of a <u>product</u>

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DSCSA Basics: Timeline

2015
Lot-level tracing implemented.

Ongoing
• Industry conversations and pilots to inform Phase II.

Nov. 27, 2020
• Dispensers must only receive serialized product.

Nov. 2021 – Nov. 2022
• Interoperability testing.

Nov. 27, 2023
• Adoption of interoperable system for electronic, unit-level tracing.

2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024

Nov. 27, 2017
(Delayed to Nov. 27, 2019)
• Manufacturers must serialize product.

Nov. 27, 2019
(Delayed to Nov. 27, 2020)
• Wholesalers must only receive serialized product.
• Wholesalers must verify saleable returns.

Jan. 2020– Dec. 2020
• Create Interoperability Blueprint

Jun. 2021 – Jun. 2022
• Build systems and processes

Nov. 2022 – Nov. 2023
• Rollout, implementation, and testing

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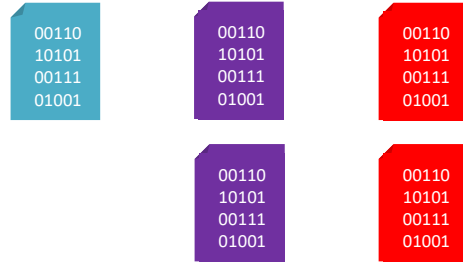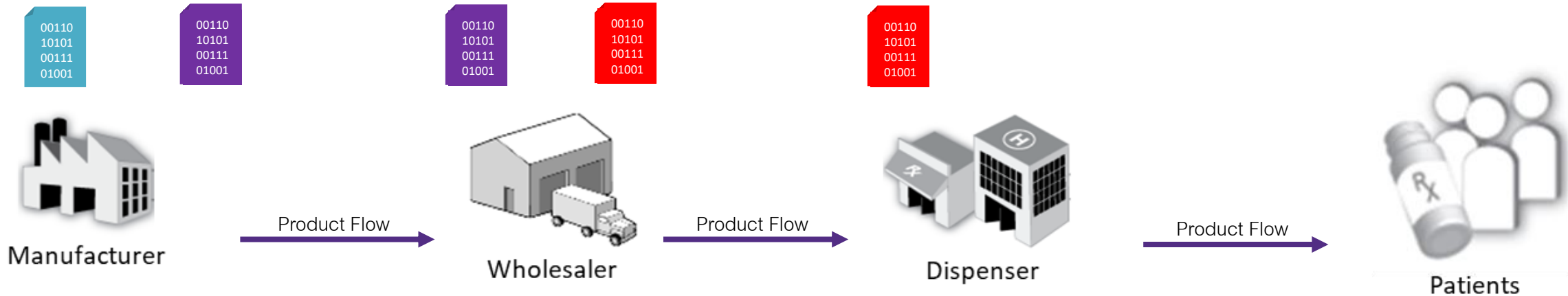
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DSCSA Basics: Tracing

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5 records per Product Identifier X 4.5 billion units distributed per year =

22.5 billion records per year

22.5 billion records per year X 6 year data retention requirement =

135 billion records in the supply chain

135 billion records in the supply chain distributed across tens of thousands of trading partners

Tracing = How do you promptly identify the 5 relevant records from the haystack of 135 billion records across tens of thousands of trading partners?

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PDG: Governance Function

- **Need:** DSCSA interoperability will require a level of cooperation, coordination, and interconnection at the unit level not present today. Efficient implementation requires an intentional implementation plan.

- **Purpose:** Develop a vision for full implementation of DSCSA interoperability and advance commitment to that vision.

- **Scope:** Interoperable verification and tracing (as required by DSCSA), including practices and processes that impact the integrity and reliability of interoperable verification and tracing.

- *More information:* www.DSCSAGovernance.org

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Upcoming: Rx-360 Town Hall Meeting

April 23rd at 9:00am EST: COVID-19 and its **Impact on the Pharmaceutical Industry in India**. Guests include Ivy Louis, and Vishal Sharma (President-Elect PDA India) from Vienni and Anish Swadi, President – Strategy and Business development at Hikal.

April 30th at 12:00pm EST: **COVID-19, The Pharma Industry, and the Next 90 Days in the UK** with Steve Nicoll, Director, The Lean Orange

Email Jim Fries at jfries@rx-360.org or Brittany Doody at bdoody@rx-360.org for details or a calendar invite.

Details will also be in our daily COVID-19 Alert and on our website