CARES Act Volume reporting from an OTC Perspective – Perrigo

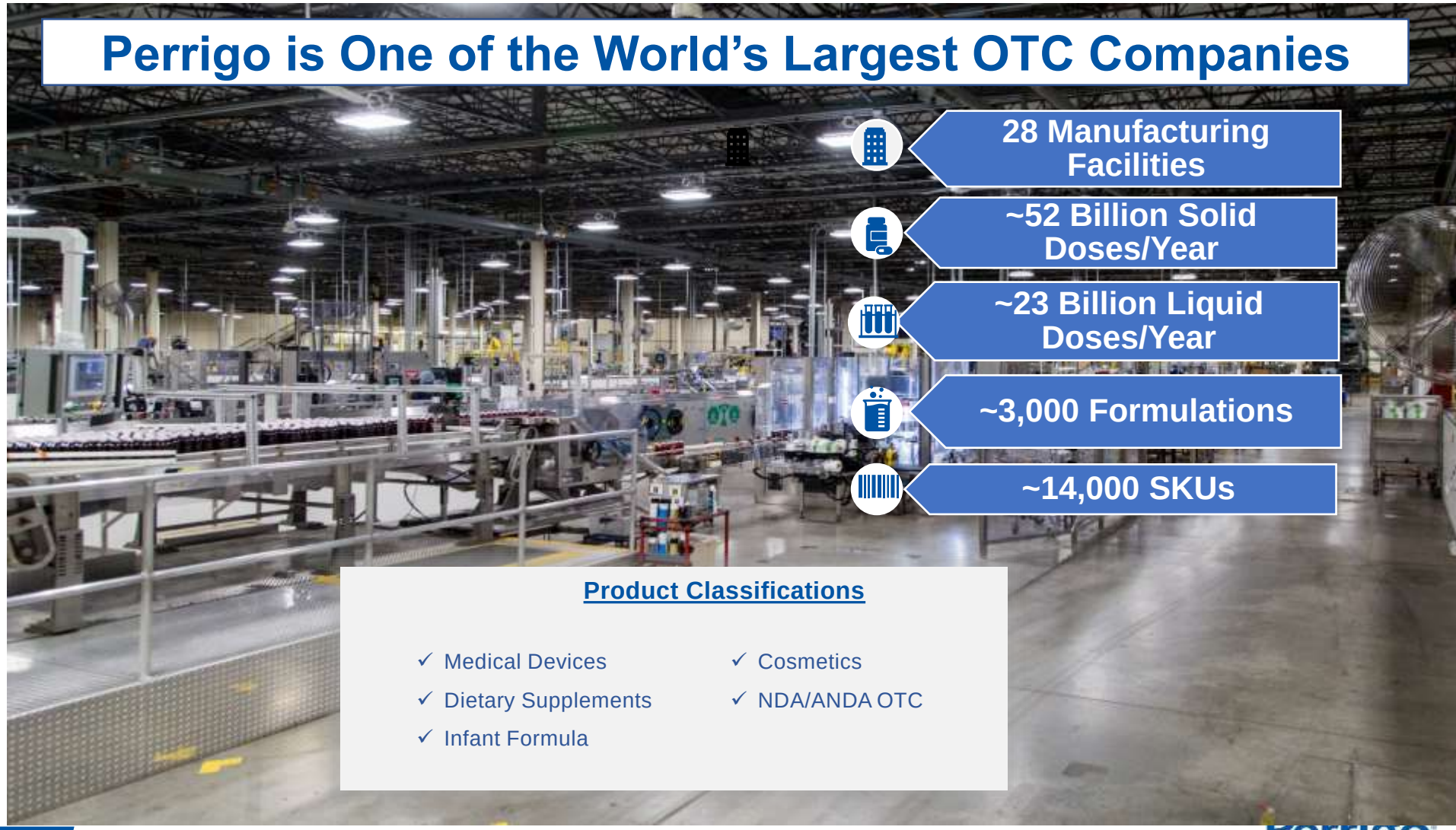
Objective

- About Perrigo
- Perrigo CARES Act Project Initiation-submission
- Suggestions
- Summary

Perrigo

Perrigo

Perrigo Overview



Perrigo is One of the World's Largest OTC Companies

- 28 Manufacturing Facilities
- ~52 Billion Solid Doses/Year
- ~23 Billion Liquid Doses/Year
- ~3,000 Formulations
- ~14,000 SKUs

Product Classifications

- ✓ Medical Devices
- ✓ Dietary Supplements
- ✓ Infant Formula
- ✓ Cosmetics
- ✓ NDA/ANDA OTC

Perrigo- Overview

CARES Act Project

- Drug Product Volume reporting Requirements Interpretation
- Kick-off Meeting
  - Core Team Established
  - Review Report Criteria

Perrigo

CARES ACT Project- Data Dive

1. **WHAT** system(s) contain the data?

SAP Excel

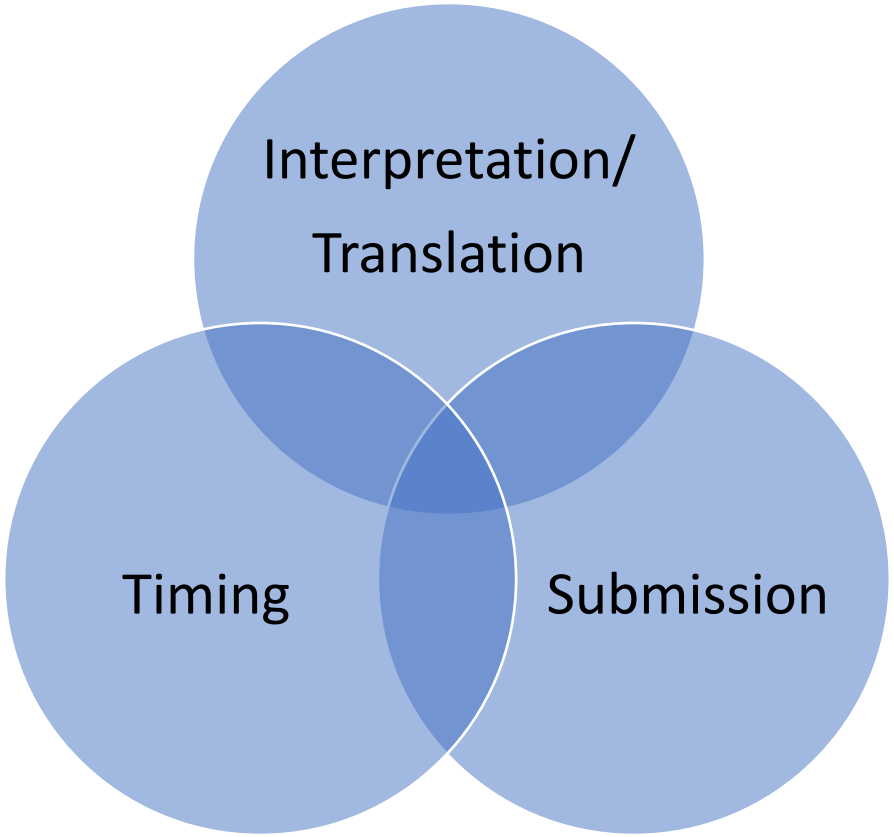
2. **WHO** can extract the data?

IT

3. **HOW** can a report be created in the required format with the required data?

Perrigo

CARES ACT Project- challenges and successes



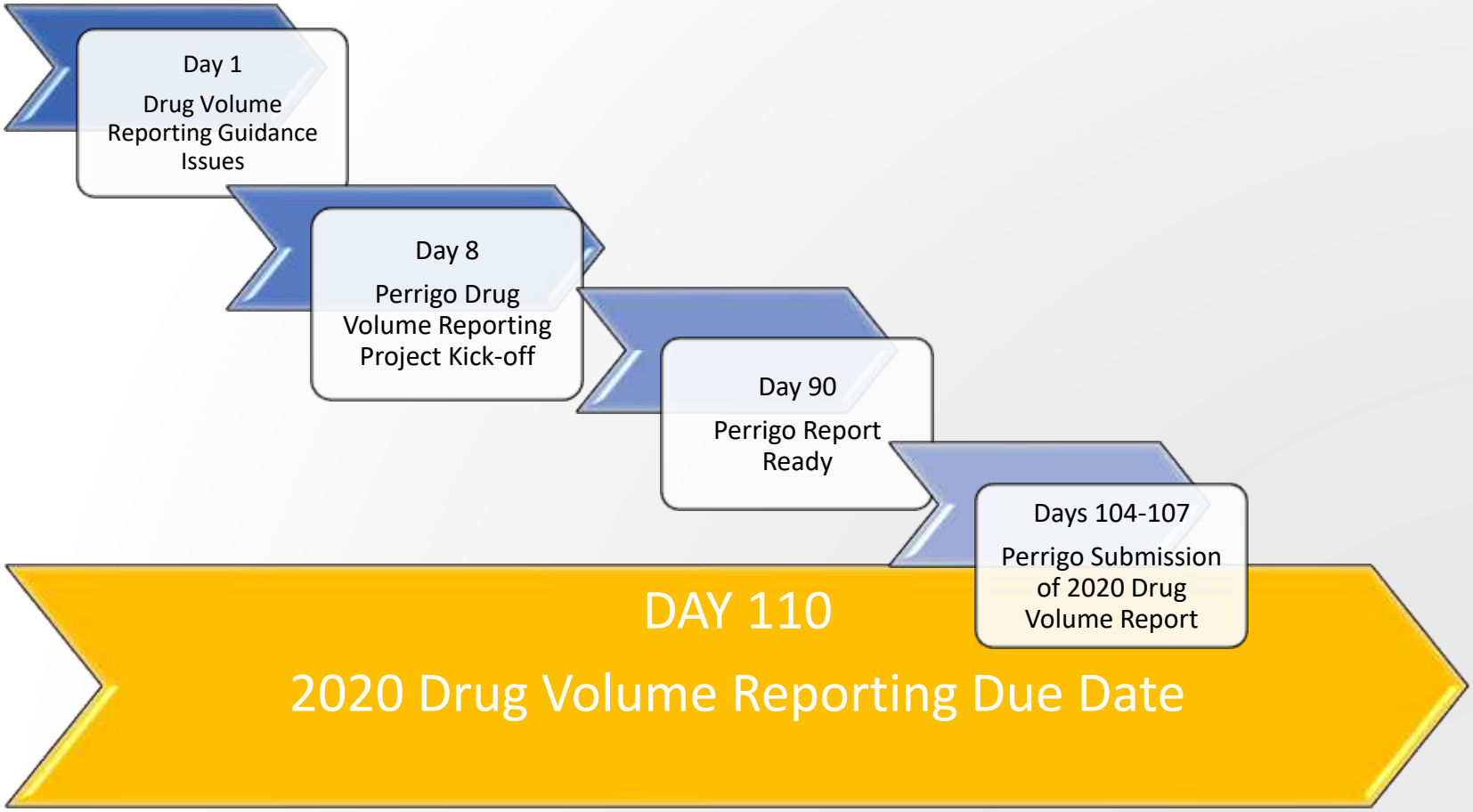
CARES ACT Project- interpretation / translation

Release

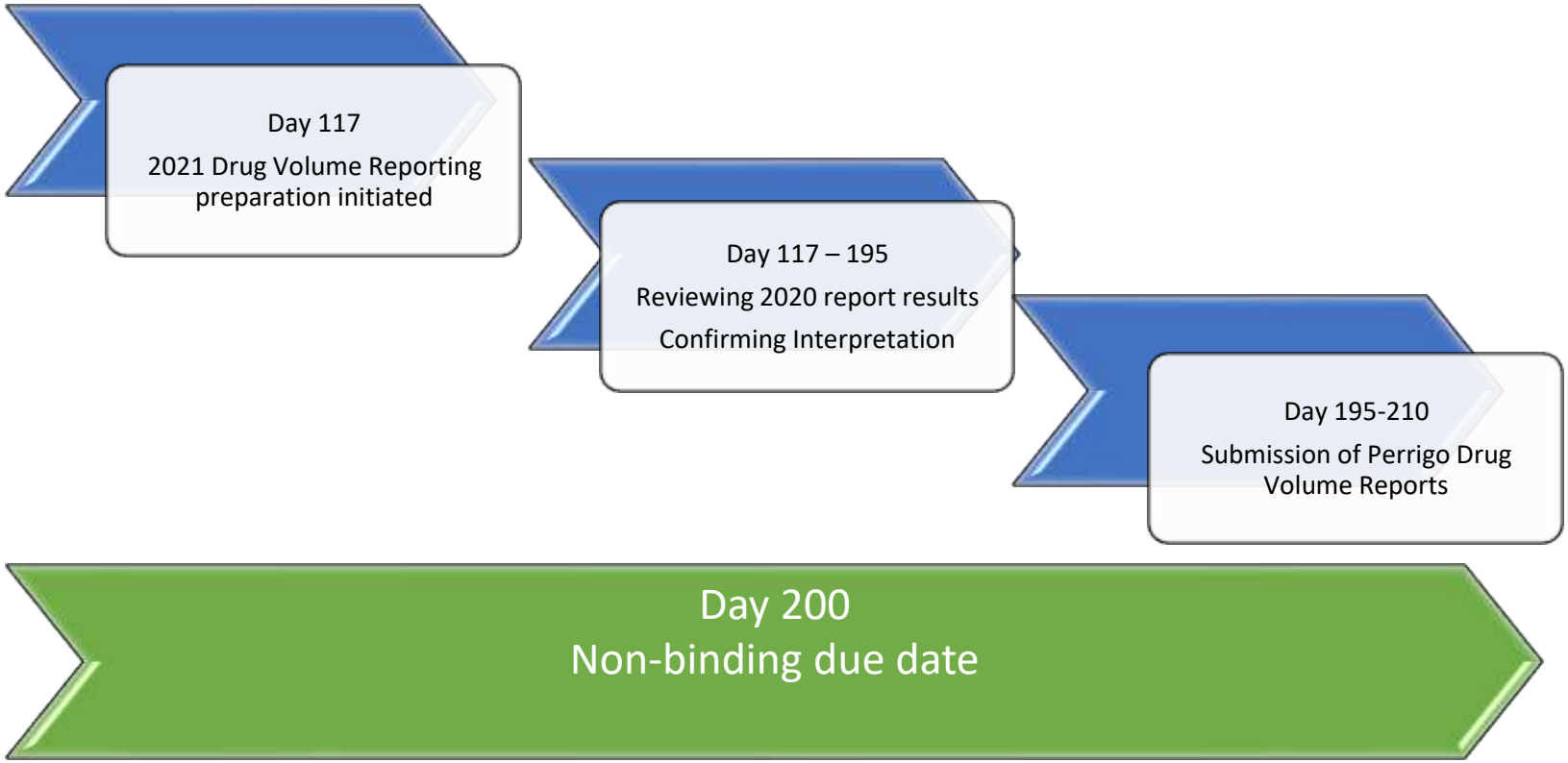
Manufacturer

Contract manufacturer

CARES ACT 2020 Report-Timing/Submission



CARES ACT -2021 Report-Timing/Submission



CARES ACT Report summary

- Perrigo Report data

	2020	2021
Submission dates	February 9-11, 2022	May 11-26, 2022
# Reports	22	5
Total rows of data	56,174	81,198
Total # of NDCs	4,321	6,246

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Suggestions

1. Are there future plans to align the definition of operations among the various requirements?

2. Are there considerations being given to limit the focus to yearly volumes for medically necessary drug products?

3. Has there been any consideration to extend the February due date to later in the year?

Summary

Was it difficult?

Did it test our systems?

Did it stretch our understanding of our internal systems and FDA requirements?

THE END

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