

# Wholesaler Utilization of AI to Support Implementation of ETASU associated with Shipment to Certified Facilities and Pharmacies

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# Disclaimer

The views and opinions expressed in this presentation are solely those of the individual presenters and do not represent or reflect any official policies or positions of their employers.

# Considerations

- It's important to understand the product medication use system/process when implementing REMS operations.
  - How is the product to be acquired by a facility? (Wholesaler-distributor, specialty pharmacy, transfer from another certified facility, directly from the manufacturer, etc.)
  - Does the treatment start as inpatient and transition to outpatient?
- Facility types can vary vastly across REMS programs (inpatient hospital pharmacy, oncology infusion center, community physician office, community pharmacies).
- It is not uncommon for healthcare settings to share NPI or DEA for purposes of purchasing from wholesaler-distributors.
- **Same NPI, Same DEA, Different address**

Facility REMS ID	NPI Number	DEA#	Pharmacy/HCS Name	Pharmacy/HCS Type	Address Line 1
000123	1234567890	BB123456	ABC HOSPITAL	Oncology Infusion Center	500 Main Street
000456	1234567890	BB123456	ABC HOSPITAL	Inpatient Hospital Pharmacy	510 Main Street

- How do you plan to verify shipping endpoints?
- What type of facility identifiers are being collected at the time of REMS enrollment/certification ?

# Current REMS Landscape at Cardinal Health



# Current REMS Landscape at Cardinal Health

- Cardinal Health currently distributes products associated with 29 active REMS programs consisting of ~145 SKUs from 35 manufacturers.
- Historically Cardinal Health has set up infrastructure to support a total of 45 REMS programs.
- 10 of the REMS Programs are Shared REMS across multiple manufacturers.
- Over the past 3 years we are seeing an average of ~10 new REMS programs launch per year.



# REMS Wholesale Distributor Challenges

- **REMS Customer Eligibility file** formats differ across programs
- REMS Customer Eligibility file identifiers differ across programs, and each identifier comes with its own challenges
  - **DEA** – Not all REMS drugs are controlled substances, but DEA has a very high level of governance and trust.
  - **NPI** – Is not considered an address specific identifier, administrators may not validate that the NPI address matches the eligible ship to address.
  - **HIN** – Rarely used across REMS programs but it is address specific and follows strict governance requirements and accuracy.
  - **Certified Facility REMS ID** – the Certified Facility REMS ID is different across all REMS programs, as a wholesaler this presents a unique challenge because we could potentially have to manage 29 or more individual REMS IDs for a single customer. Not sure if all REMS IDs are address specific or would change with an address change.
  - **Address Verification** – is a challenge because addresses do not always follow the same governance across manufacturers and REMS administrators. There are many elements to an address to match on.
  - REMS Programs/Administrators are not validating "address specific" identifiers noted above, match the physical ship to account address.
- **REMS Sales Reporting** – Some REMS programs accept the EDI 867 as a standard for reporting REMS sales to customers; others require unique reports that contain additional information not in the 867 Such as a REMS ID, serial number, etc.
  - REMS sales reports are not standardized so there are many versions that each require validation.



# FDA PART 11 COMPLIANT VALIDATED REMS SOLUTION

**The increasing volume, complexity, and variability of REMS programs necessitated systematic support to manage customer verification, streamline reporting, mitigate risk, and improve operational efficiency**

## **REMS Solution Phase 1 – Launched July 2024**

- Implemented a validated system for REMS eligibility management
- Automated eligibility file retrieval from administrator sFTP sites
- Systematically integrated eligibility data into SAP ERP
- Established secure audit trail and validated end-to-end process
- Automated 17 REMS programs

## **REMS Solution Phase 2 – Launched July 2025**

- Weekly shipment reports to REMS administrators became automated
- REMS Solution tool created for manual address verification



## FDA PART 11 COMPLIANT VALIDATED REMS SOLUTION

REMSLogout

Select REMS Program

031 [REDACTED]

[Add or Maintain Ship-to](#)

[REDACTED]

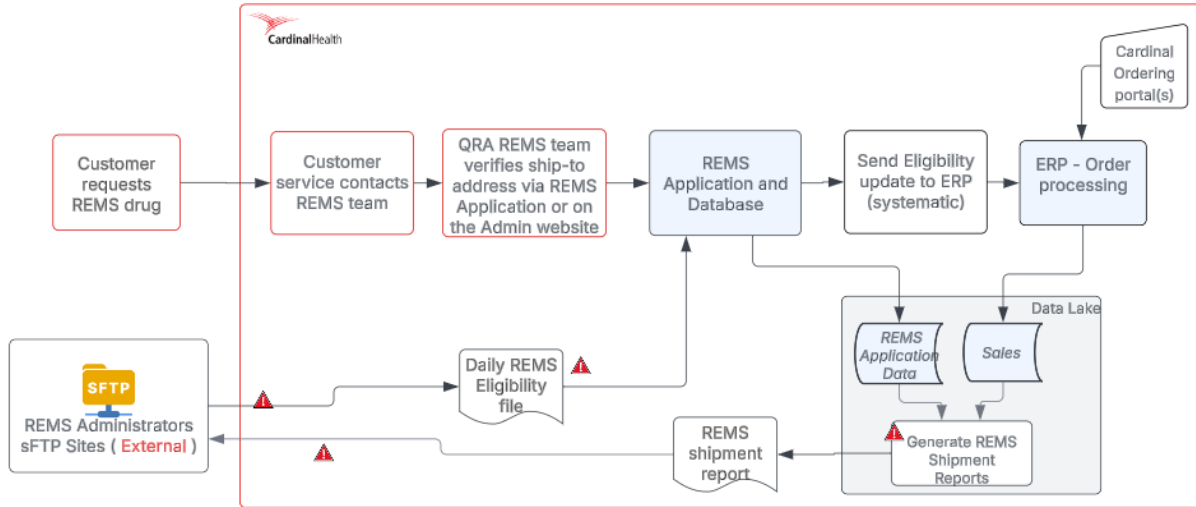
Customer exists on the Approved customer list

Status: **Approved** Last Updated : 2/16/26

Cardinal Customer Master(current)	Verified/Saved Address				
<p><b>Name:</b> [REDACTED]</p> <p><b>Name 2:</b> [REDACTED]</p> <p><b>Address:</b> [REDACTED]</p> <p><b>Address 2:</b> [REDACTED]</p> <p><b>City:</b> [REDACTED]</p> <p><b>State:</b> [REDACTED]</p> <p><b>Zip:</b> [REDACTED]</p> <p><b>DEA#:</b> [REDACTED]</p> <p><b>NPI:</b> [REDACTED]</p> <p><b>NCPDP:</b> [REDACTED]</p> <p><b>HIN:</b> [REDACTED]</p> <p><b>Customer Group:</b> PHCY</p> <p><b>Customer classification:</b> RETAIL INDEPENDENT</p>	<table border="1"><thead><tr><th>Cardinal Customer Master</th><th>REMS Eligibility File</th></tr></thead><tbody><tr><td><p><b>Name:</b> [REDACTED]</p><p><b>Name 2:</b> [REDACTED]</p><p><b>Address:</b> [REDACTED]</p><p><b>Address 2:</b> [REDACTED]</p><p><b>City:</b> [REDACTED]</p><p><b>State:</b> [REDACTED]</p><p><b>Zip:</b> [REDACTED]</p><p><b>DEA#:</b> [REDACTED]</p><p><b>NPI:</b> [REDACTED]</p><p><b>NCPDP:</b> [REDACTED]</p><p><b>HIN:</b> [REDACTED]</p></td><td><p><b>REMS ID:</b> [REDACTED]</p><p><b>Name:</b> [REDACTED]</p><p><b>Name 2:</b> [REDACTED]</p><p><b>Address:</b> [REDACTED]</p><p><b>Address 2:</b> [REDACTED]</p><p><b>City:</b> [REDACTED]</p><p><b>State:</b> [REDACTED]</p><p><b>Zip:</b> [REDACTED]</p><p><b>DEA#:</b> [REDACTED]</p><p><b>NPI:</b> [REDACTED]</p><p><b>NCPDP:</b> [REDACTED]</p><p><b>HIN:</b> [REDACTED]</p></td></tr></tbody></table>	Cardinal Customer Master	REMS Eligibility File	<p><b>Name:</b> [REDACTED]</p> <p><b>Name 2:</b> [REDACTED]</p> <p><b>Address:</b> [REDACTED]</p> <p><b>Address 2:</b> [REDACTED]</p> <p><b>City:</b> [REDACTED]</p> <p><b>State:</b> [REDACTED]</p> <p><b>Zip:</b> [REDACTED]</p> <p><b>DEA#:</b> [REDACTED]</p> <p><b>NPI:</b> [REDACTED]</p> <p><b>NCPDP:</b> [REDACTED]</p> <p><b>HIN:</b> [REDACTED]</p>	<p><b>REMS ID:</b> [REDACTED]</p> <p><b>Name:</b> [REDACTED]</p> <p><b>Name 2:</b> [REDACTED]</p> <p><b>Address:</b> [REDACTED]</p> <p><b>Address 2:</b> [REDACTED]</p> <p><b>City:</b> [REDACTED]</p> <p><b>State:</b> [REDACTED]</p> <p><b>Zip:</b> [REDACTED]</p> <p><b>DEA#:</b> [REDACTED]</p> <p><b>NPI:</b> [REDACTED]</p> <p><b>NCPDP:</b> [REDACTED]</p> <p><b>HIN:</b> [REDACTED]</p>
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# FDA VALIDATED REMS SOLUTION



▲ Processes requiring customization for each new program

## REMS Program Onboarding (2 - 4 Weeks)

- Team assembly & kickoff (manufacturer/administrator)
- Data Interchange Agreement & eligibility requirements confirmed
- Administrator provides sFTP access
- IT configures file mapping & reports
- Validation testing
- Item Master data updates
- Program launch



# REMS Eligibility Approval using AI and Machine Learning

## REMS Solution Phase 3 – Targeted July 2026

### Challenge: Customer Master Data Matching

500K+ accounts: 50+ associates company-wide perform inconsistent, manual matching daily

#### Complexity/Barriers for Automation:

- Data inconsistencies
- Manual curation for accurate matches
- Complex rule and code development needed

### Solution: Customer Master Data Matching using AI/ML

Machine Learning-driven solution created for improved customer matching

- Natural Language Processing (NLP) for data curation
- Scientific scoring (name/address)
- Geographic distance assessment
- Continuous model refinement(user feedback)

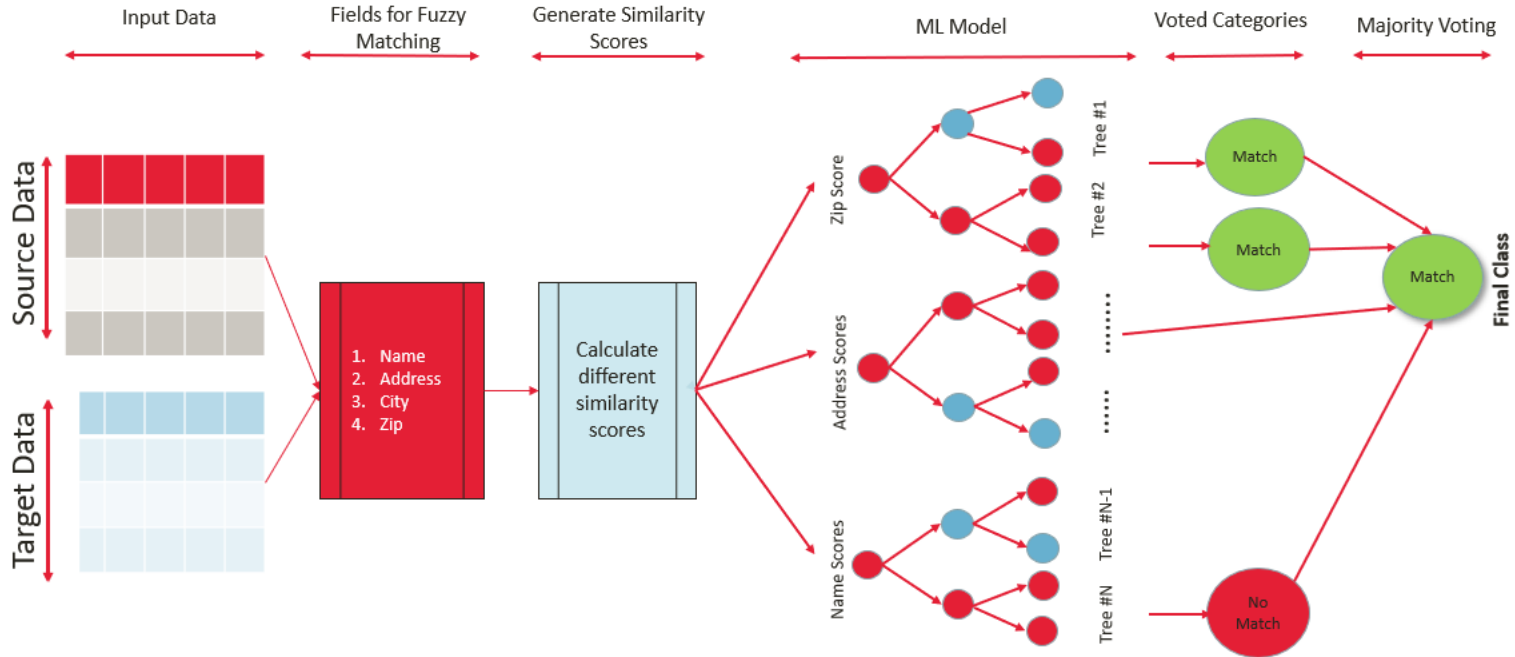
### Solution Use Case: REMS Eligibility Automation

Leverage AI/ML driven in-house address verification to enhance compliance, efficiency, and scale

- Configurable to meet specific REMS program requirements
- Manual verification option remains available

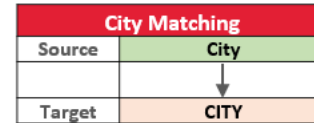
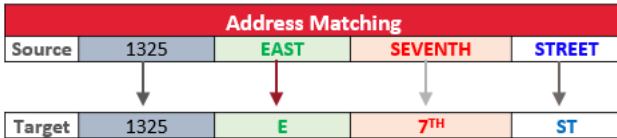
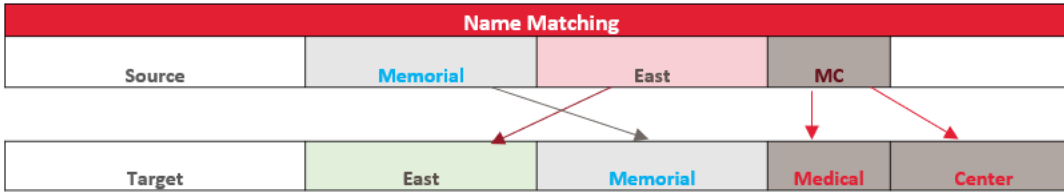


# Address matching using AI and Machine Learning



# Address Matching Example

Name	Address	City	Zip
Memorial East MC	1325 EAST SEVENTH STREET	City	12345
East Memorial Medical Center	1325 E 7TH ST	CITY	12345



Name	Address	City	Zip	Prediction	Probability	Geo distance
Memorial East MC	1325 EAST SEVENTH STREET	City	12345			
East Memorial Medical Center	1325 E 7TH ST	CITY	12345	Match	89	0.0



# REMS Best Practices and Lessons Learned

- **Standardization** of REMS identifiers, inbound/outbound reports would greatly streamline product launches
  - File Type (.csv, .txt , .xlsx etc..) and delimiter
  - Attributes and column order in the Eligibility file
  - Attributes and column order in the Shipment file
- As much runway manufacturers can provide distributors prior to launch the better.
- Up front training on the REMS program requirements goes a long way!
- Clearly detail and align on eligibility requirements.
  - **Avoid any assumptions** (REMS Identifiers, Address Verification, combination, etc.)
  - Confirm if address verification is required in addition to REMS identifier (DEA, NPI, HIN, NCPDP) matching and if it is, to what extent is address verification required (address only, address plus customer name or department/suite match).
  - It is key to understand if REMS administrators are verifying the REMS identifier addresses match the authorized/eligible customer address.

