

# A New Approach to Handling Two Concurrent Nirsevimab Submissions in the New York City IIS

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# Outline

- Burden of respiratory syncytial virus (RSV)
- Nirsevimab recommendations
- Citywide Immunization Registry (CIR)
- A new challenge for IIS jurisdictions
- CIR solution
  - Step 1: Handling two inbound nirsevimab submissions in front-end data processing
  - Step 2: Updated logic in back-end immunization de-deduplication algorithm
- Results
- Special considerations for data quality
- Conclusions

# Burden of Respiratory Syncytial Virus

- Respiratory syncytial virus (RSV) is a common respiratory virus that usually causes mild, cold-like symptoms
- RSV season typically begins in November and lasts through April in the U.S.\*
- RSV is a major cause of morbidity and mortality among children aged <5 years
  - RSV is associated with an annual estimate of\*\*:
    - 100 – 300 deaths
    - 58,000 – 80,000 hospitalizations
    - Nearly 520,000 emergency department visits
    - Approximately 1,500,000 outpatient visits

\*Prescribing information for SYNAGIS [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/103770s5185lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103770s5185lbl.pdf)

\*\*ACIP Evidence to Recommendations for Use of Nirsevimab in Infants born during the RSV season or entering their first RSV season

<https://www.cdc.gov/acip/evidence-to-recommendations/nirsevimab-season1-rsv-infants-children-etr.html>

# Nirsevimab Recommendations

# Nirsevimab Recommendations:

- In August 2023, the Advisory Committee on Immunization Practices (ACIP) recommended the use of nirsevimab (BEYFORTUS) in two age groups in infants and children\*
- Nirsevimab is available in two presentations:

- 50 mg (CVX 306)



- 100 mg (CVX 307)



# Nirsevimab Recommendations (1): Among Infants 0 – 7 months

- ACIP recommends one dose of nirsevimab for infants aged 0 – 7 months entering their first RSV season\* (unless a valid maternal RSV vaccine was during pregnancy)
  - 50 mg (CVX 306) for infants weighing <5 kg
  - 100 mg (CVX 307) for infants weighing ≥5 kg



# Nirsevimab Recommendations (2): Among Infants and Children 8 – 19 months

- ACIP recommends one dose of nirsevimab for infants and children aged 8 – 19 months who are at increased risk for severe RSV disease (estimated <5% of infants) and entering their second RSV season\*
- 200 mg, administered as two 100 mg (CVX 307) injections given at the same time

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Definition: CVX is a code set maintained by the Centers for Disease Control and Prevention. <https://www.cdc.gov/iis/code-sets/index.html>

\*Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children <http://dx.doi.org/10.15585/mmwr.mm7234a4>

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- 200 mg, administered as two 100 mg (CVX 307) injections given at the same time

- Providers would be reporting two CVX 307 to immunization registries



# Citywide Immunization Registry

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- New York City's (NYC) Immunization Information System (IIS)
  - Implemented citywide in 1997
- Population-based
  - Birth certificates loaded into CIR twice a week
- Mandatory reporting of immunizations for children 0-18 years
  - Reporting for adults  $\geq$  19 years requires consent
- Contains >15 million patient records and >180 million immunizations
- Reporting methods:
  - 93% HL7 Web Service
  - 7% User interface (Online Registry)

# A New Challenge for IIS Jurisdictions

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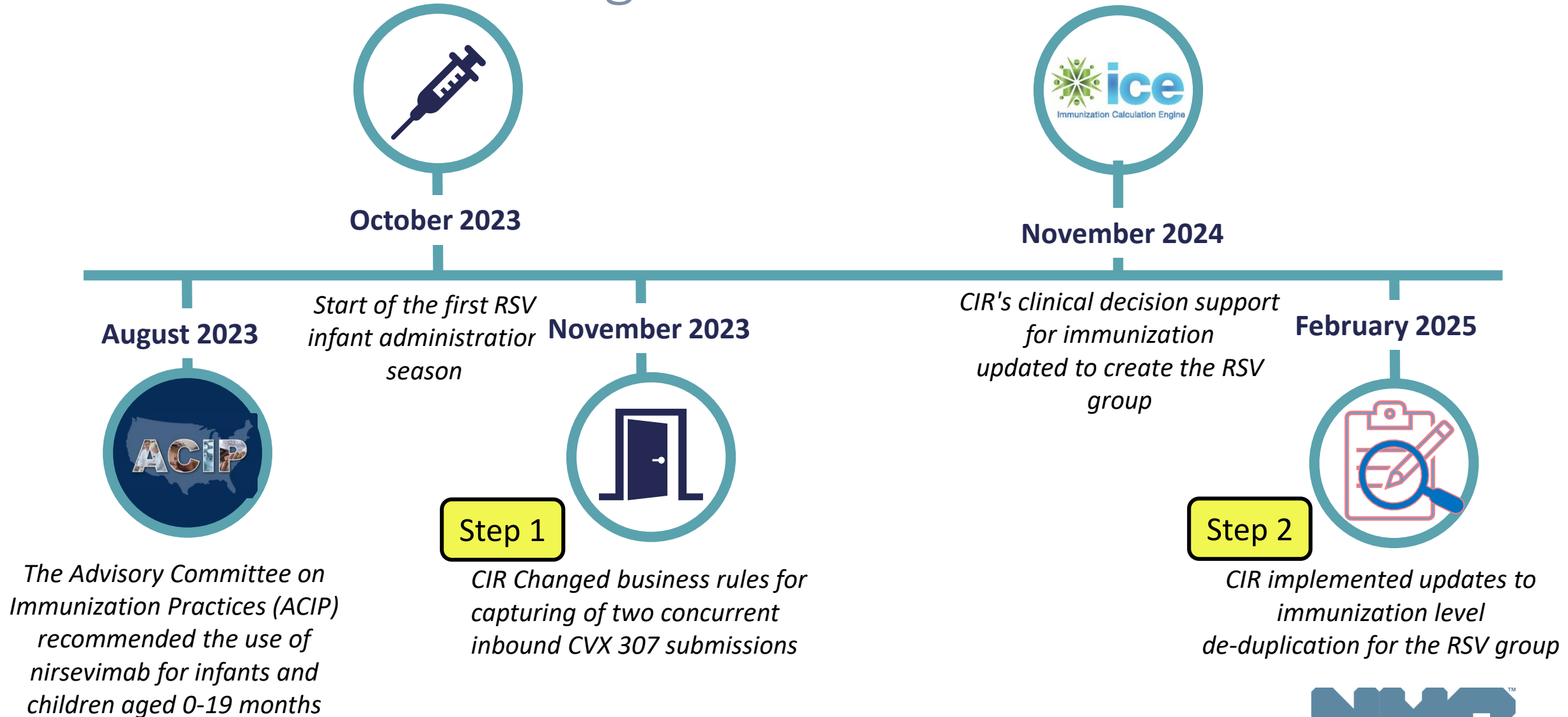
- CIR was well established to manage duplicate immunization records off by 0 to 2 days apart following AIRA's best practice guidance\*
- Reporting of a true administration of two concurrent shots of the same product on the same date is new to IIS jurisdictions
- There is no flag to indicate it is the second shot in HL7 messages
- At the same time, duplicate data are commonly sent to IIS jurisdictions
- A challenge in distinguishing concurrent shots from duplicate shots

# CIR Solution

# A Two-step Approach Solution

1. Developed new business rules to allow capture of two 100 mg of nirsevimab submissions (CVX 307) on the same date in the front end (before data entering to the CIR) at CIR Middle Tier Services
2. Updated logic to the existing immunization de-deduplication algorithm in the back end (after data entering to the CIR) to correctly evaluate previously-added shots within the RSV group

# Timeline of Handling Nirsevimab Data in CIR



## Step 1

# Handling Two Inbound Nirsevimab Submissions in Front-end Data Processing

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- In November 2023, the CIR implemented changes in its front-end processing (Middle Tier Services) and core database to allow the capture of two concurrent 100 mg nirsevimab (CVX 307) shots
  - A new '**occurrence**' field is created for inbound immunization data
  - Inbound immunization data is defaulted with **occurrence** equal to 1
    - Typically, if a 2nd shot of the same CVX with the same date of immunization for the same patient is sent, then it would be treated as an update to the existing immunization
  - **Exception** (conditions where **occurrence** can be greater than 1):
    - CVX: 307
    - Patient age at administration: 8 – 19 months
    - Up to two occurrences are allowed

# Use of Middle Tier Services in CIR System

- Middle Tier Services (MTS): a middle tier software to define and handle business rules and data access before data entering to the CIR system
  - Example: inbound immunization data

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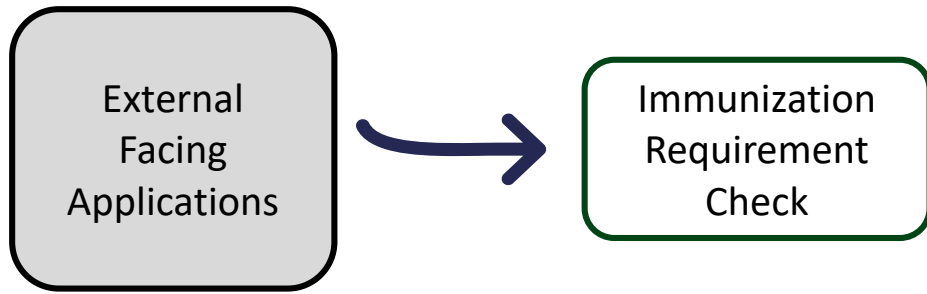
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External  
Facing  
Applications

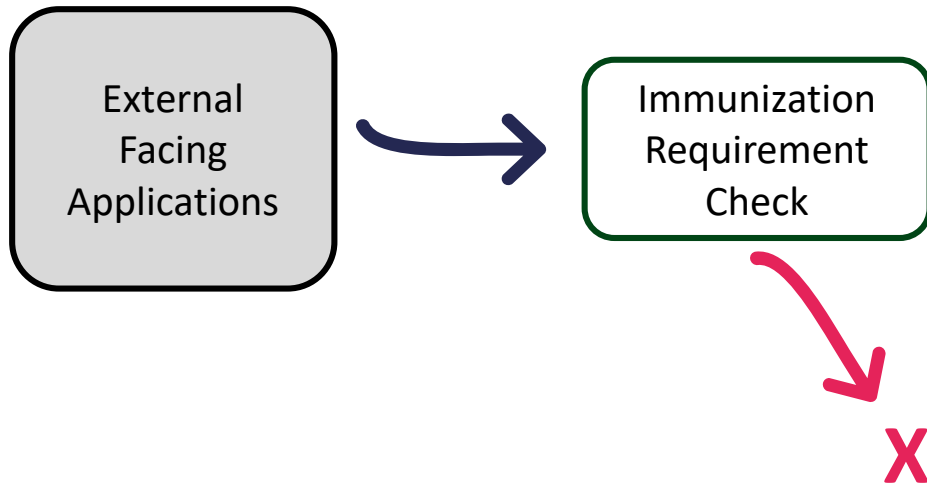
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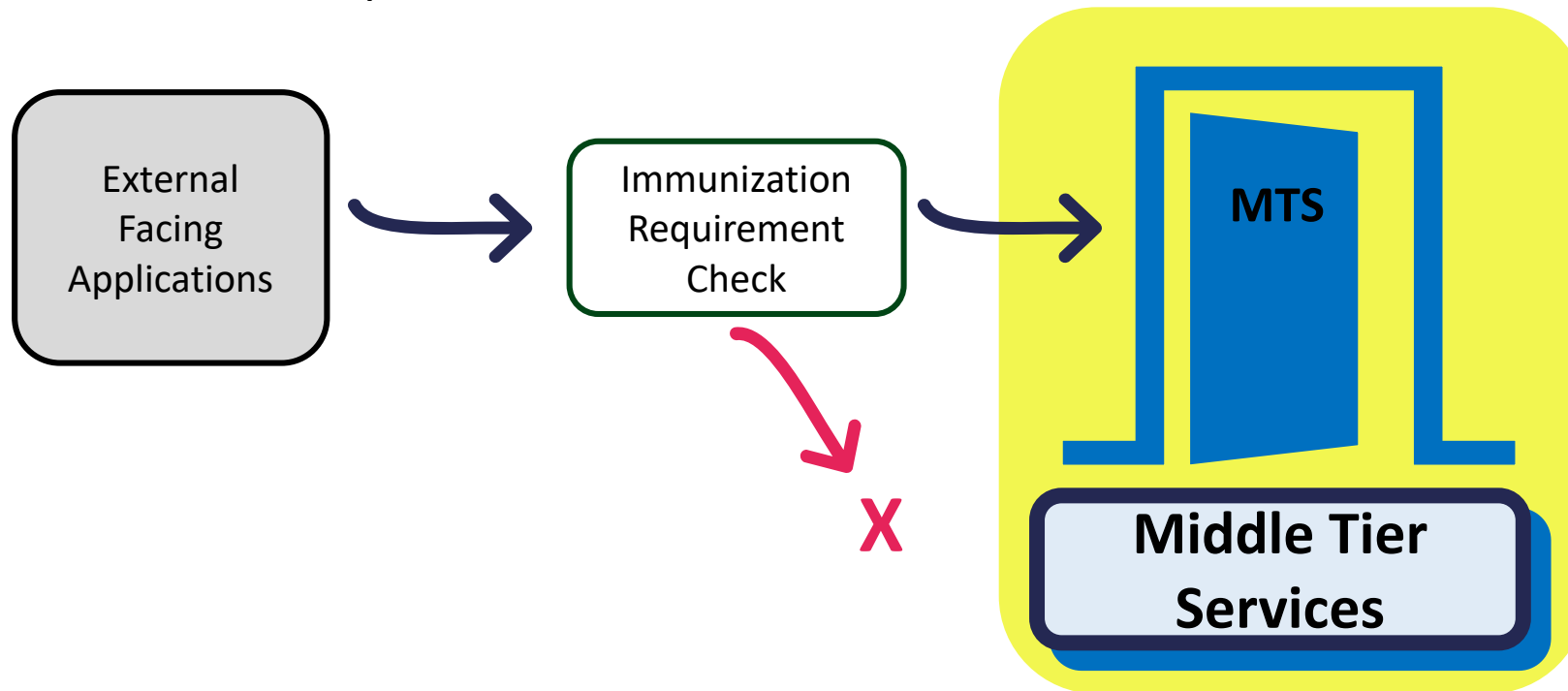
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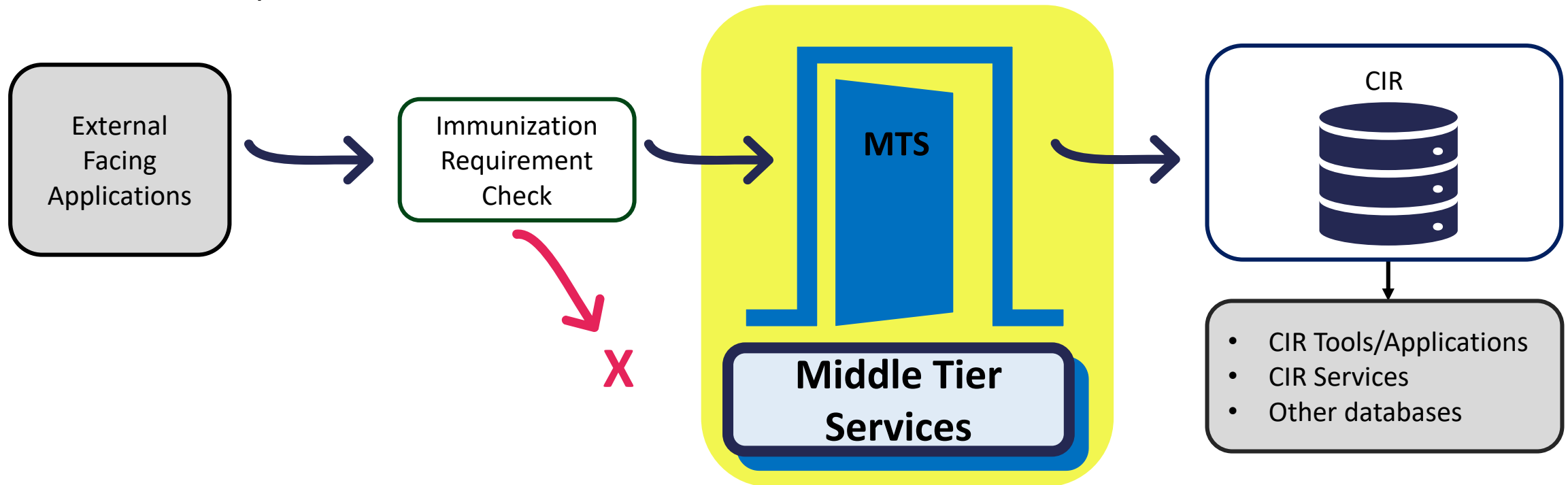
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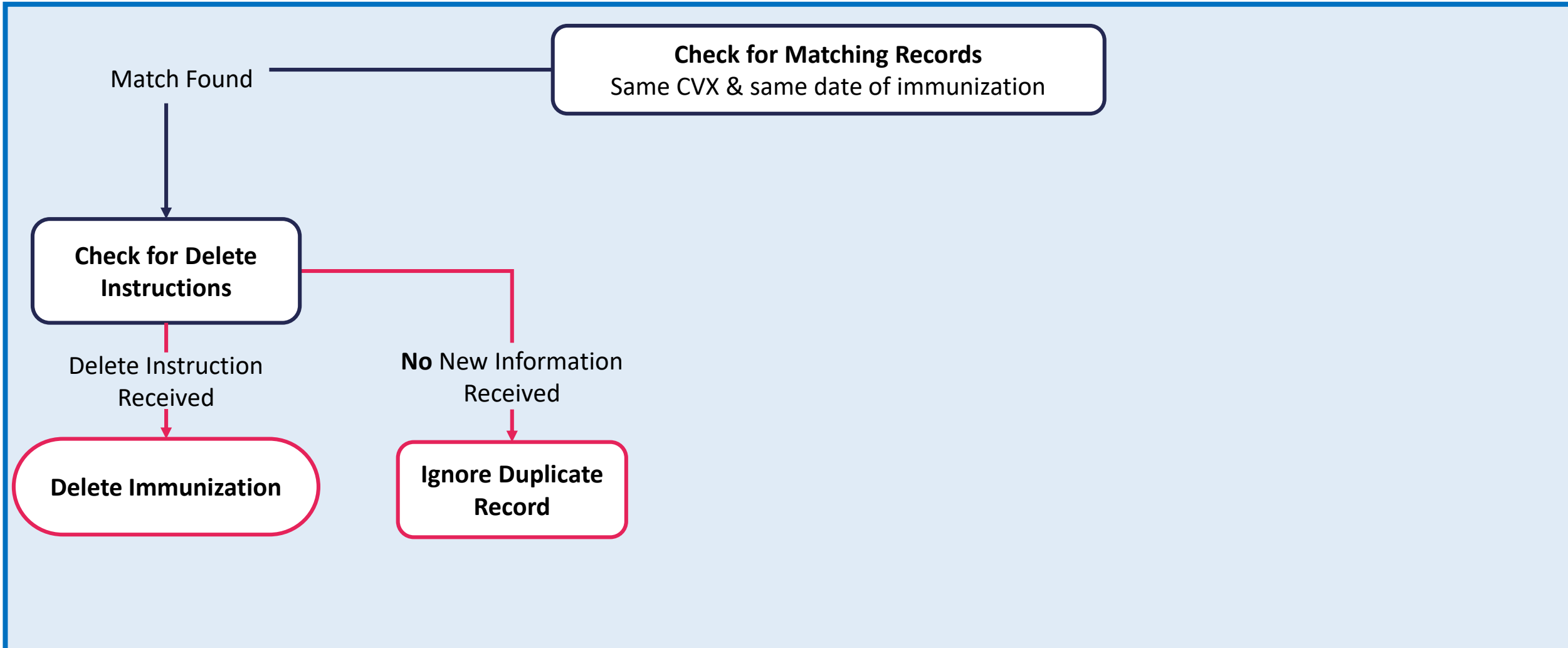
**Check for Matching Records**

Same CVX & same date of immunization

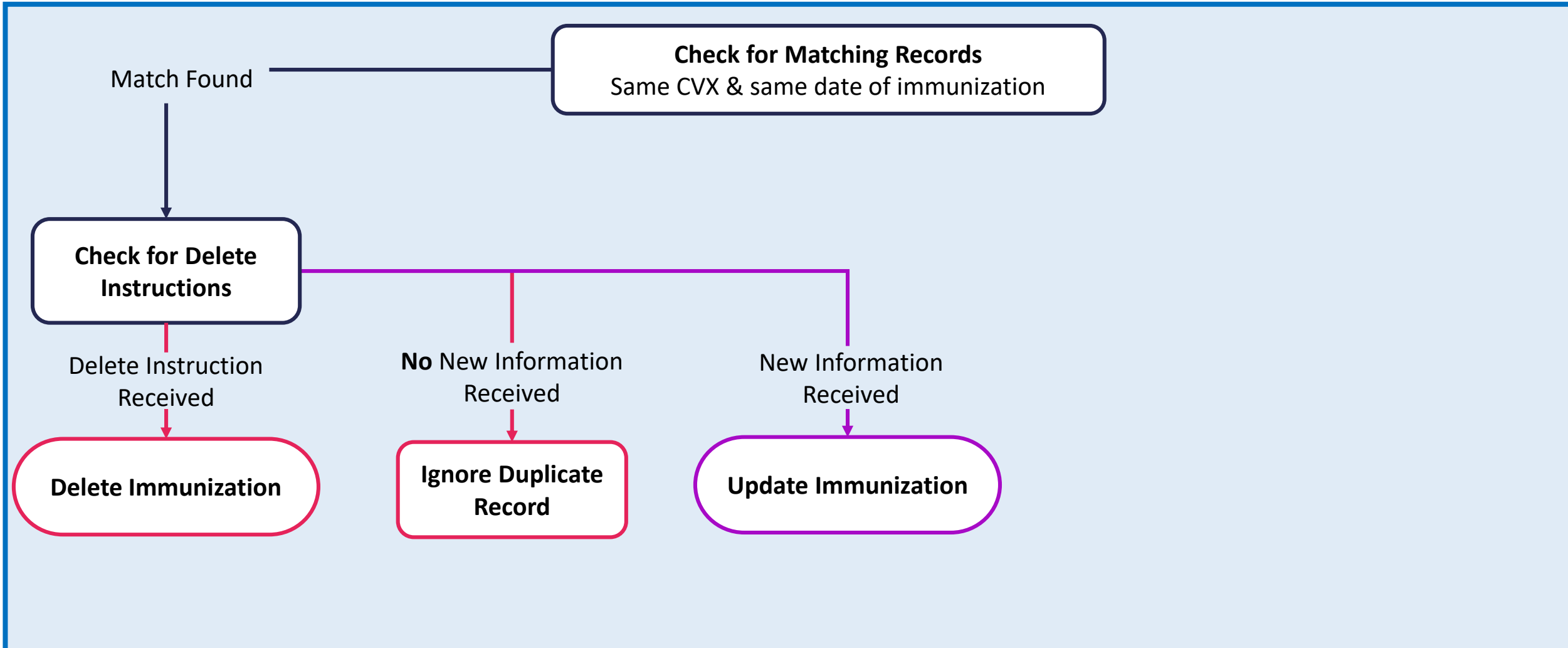
# Immunization Data Flow through MTS



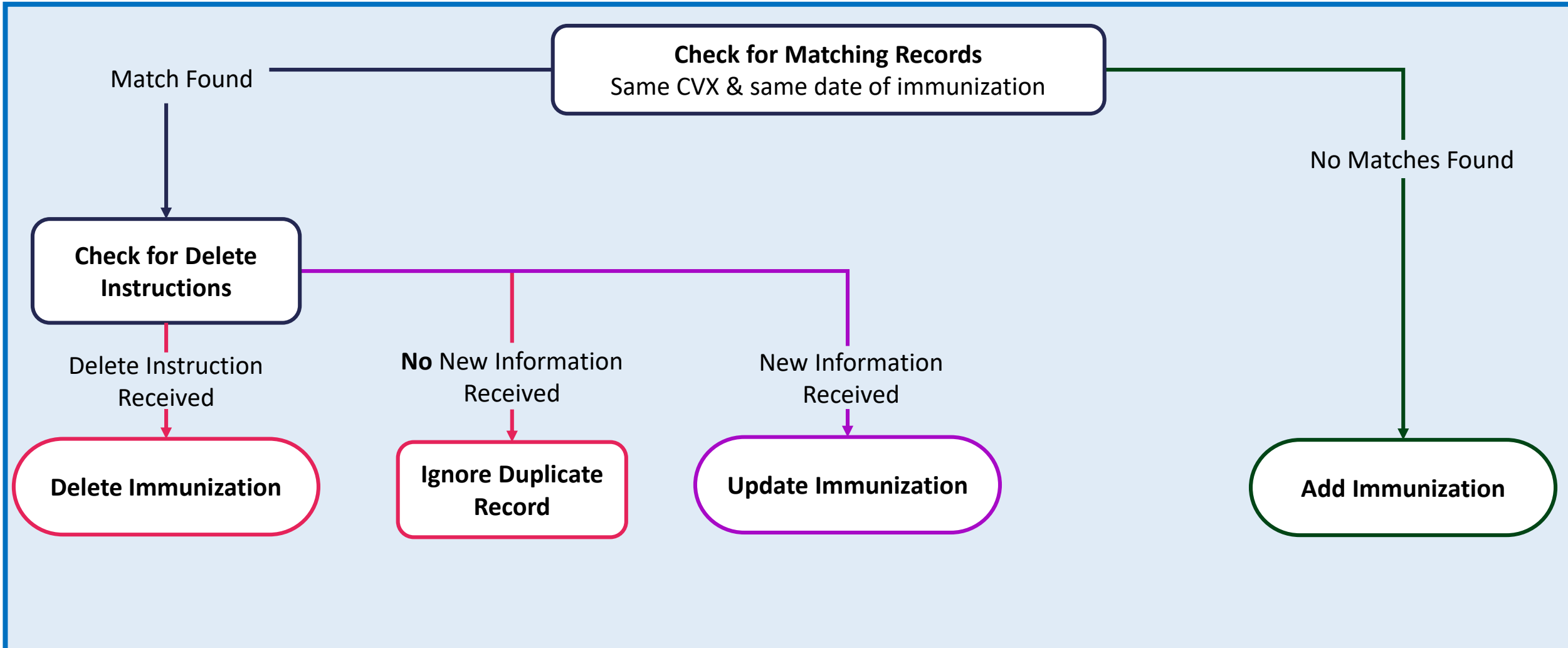
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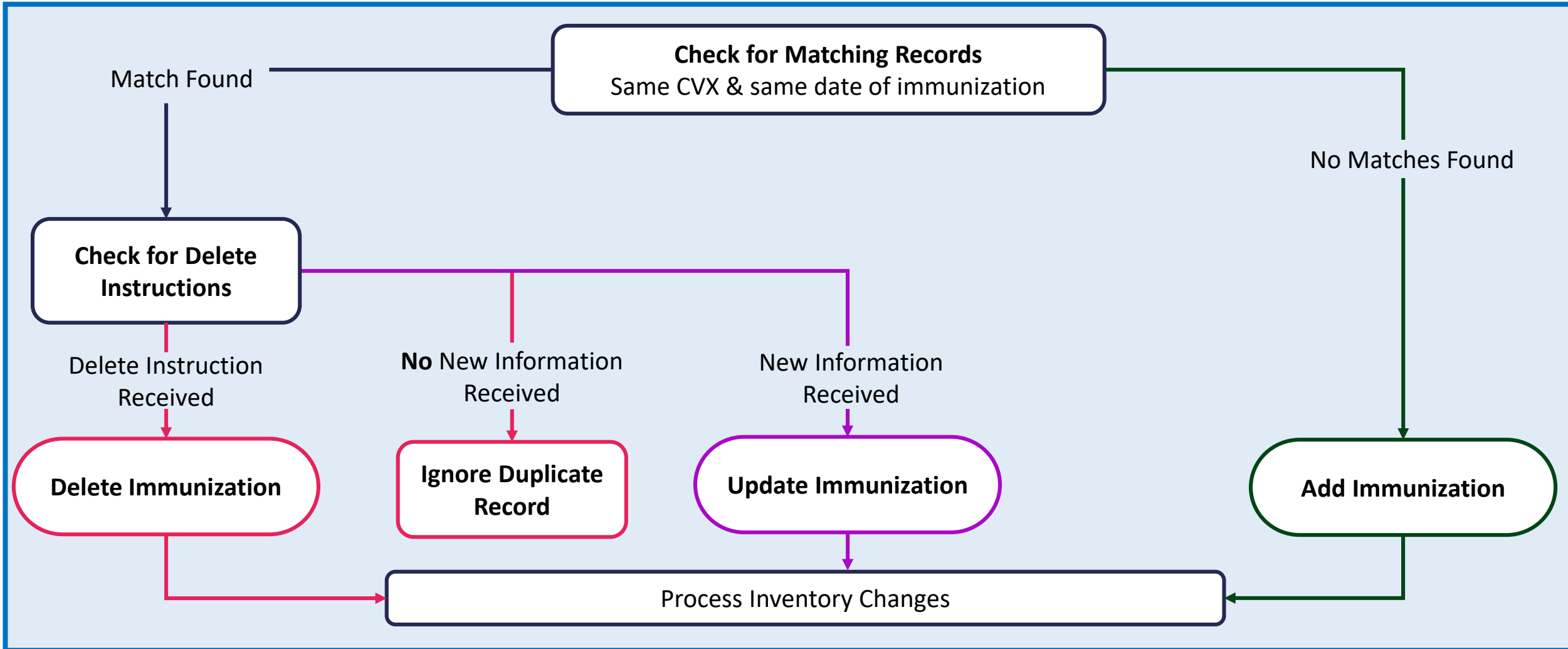
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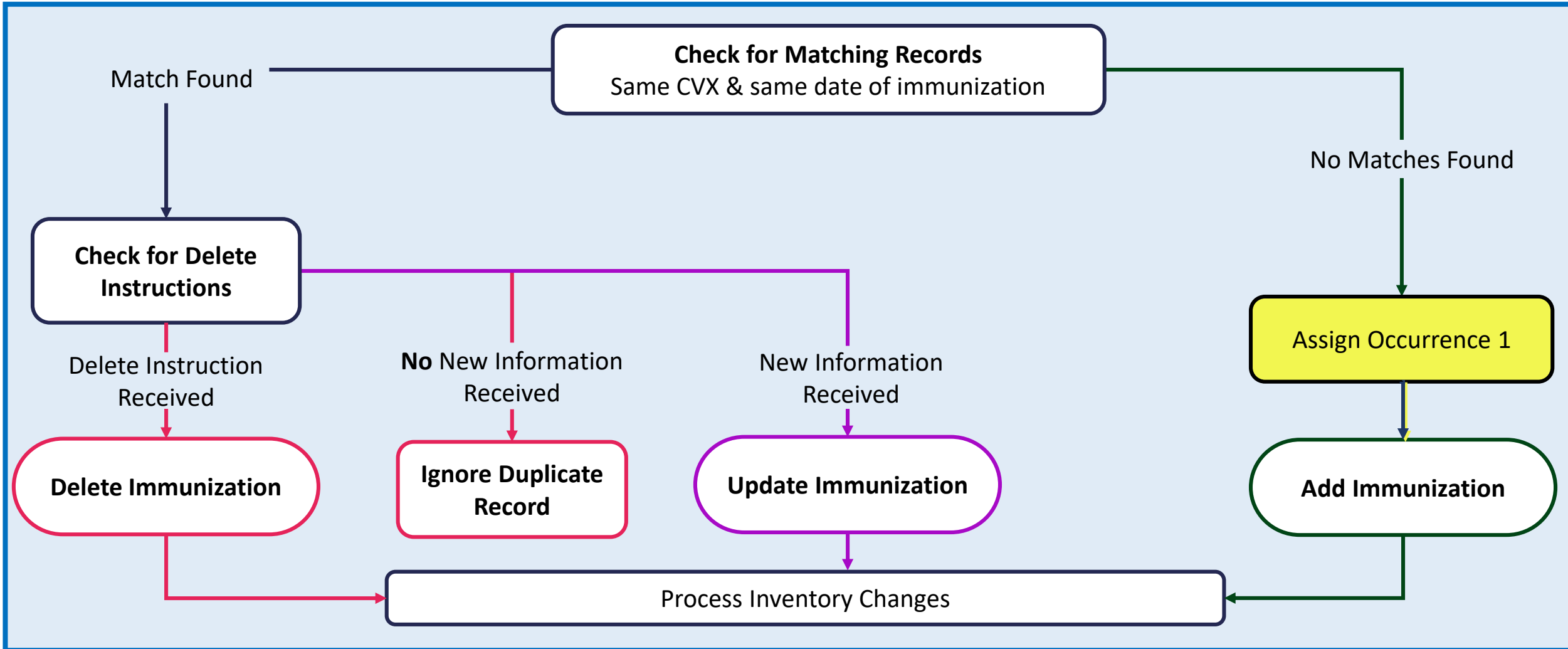


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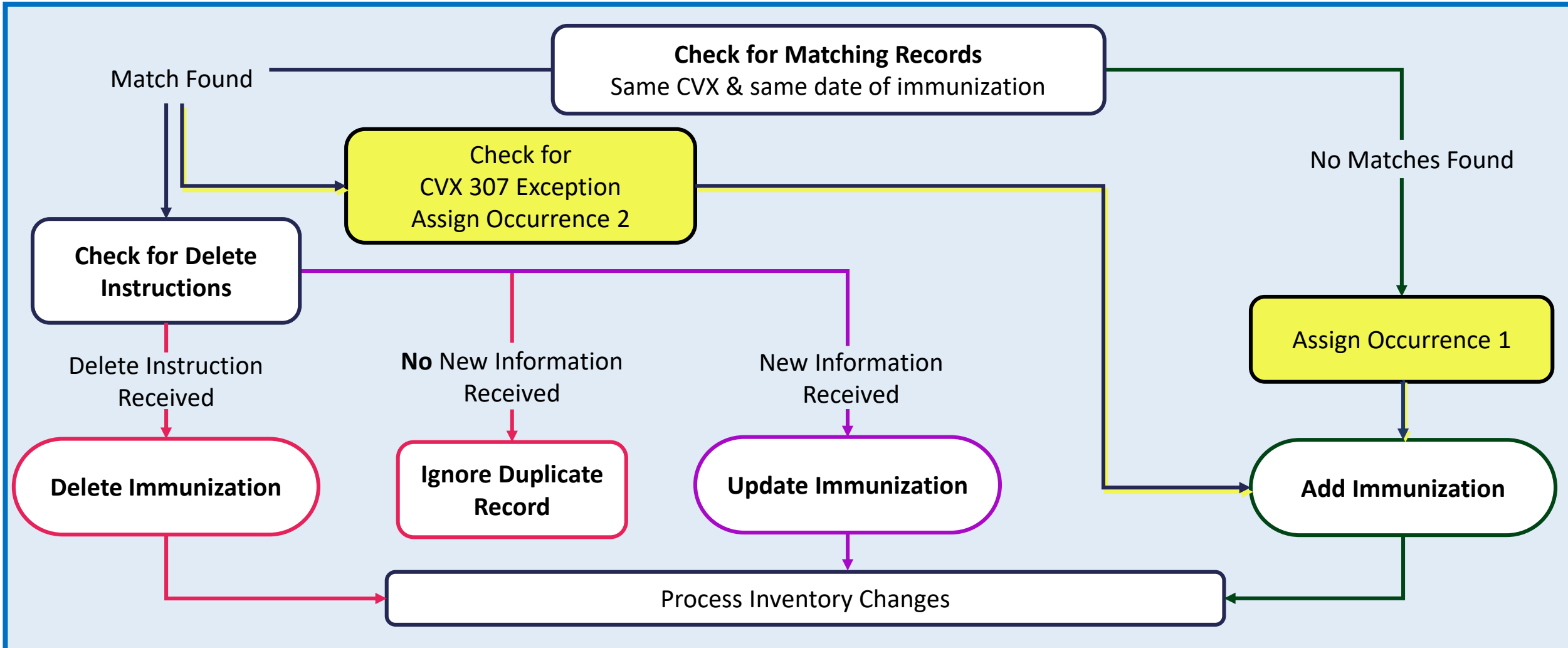
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## New Business Rules



# Immunization Data Flow through MTS

New Business Rules


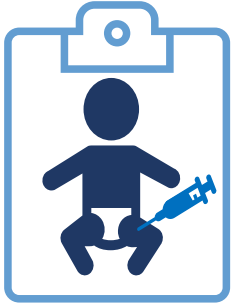
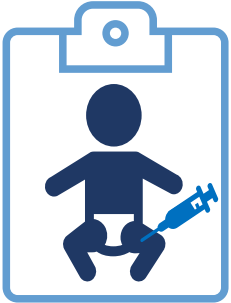
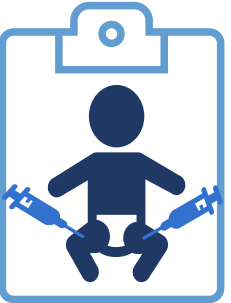


## Step 2

Updated Logic in Back-end Immunization  
De-deduplication Algorithm

# Step 2: Updated Logic in Back-end Immunization De-deduplication Algorithm

- Create a pair identification logic among those with occurrences of 1 and 2 to determine whether they are a true pair (concurrent shots)

	<p>If interval between the two shots is <b><math>\geq 45</math> minutes</b>: <b>two</b> immunization events (at least one of them is a duplicate)</p>		
	<p>If interval between the two shots <b><math>&lt; 45</math> minutes</b>: <b>same</b> immunization event</p>		<p>Assign a <b>companion ID</b> The two shots remain in the database as a pair</p>

# Immunization De-duplication: Selection

## 1. Selection Phase

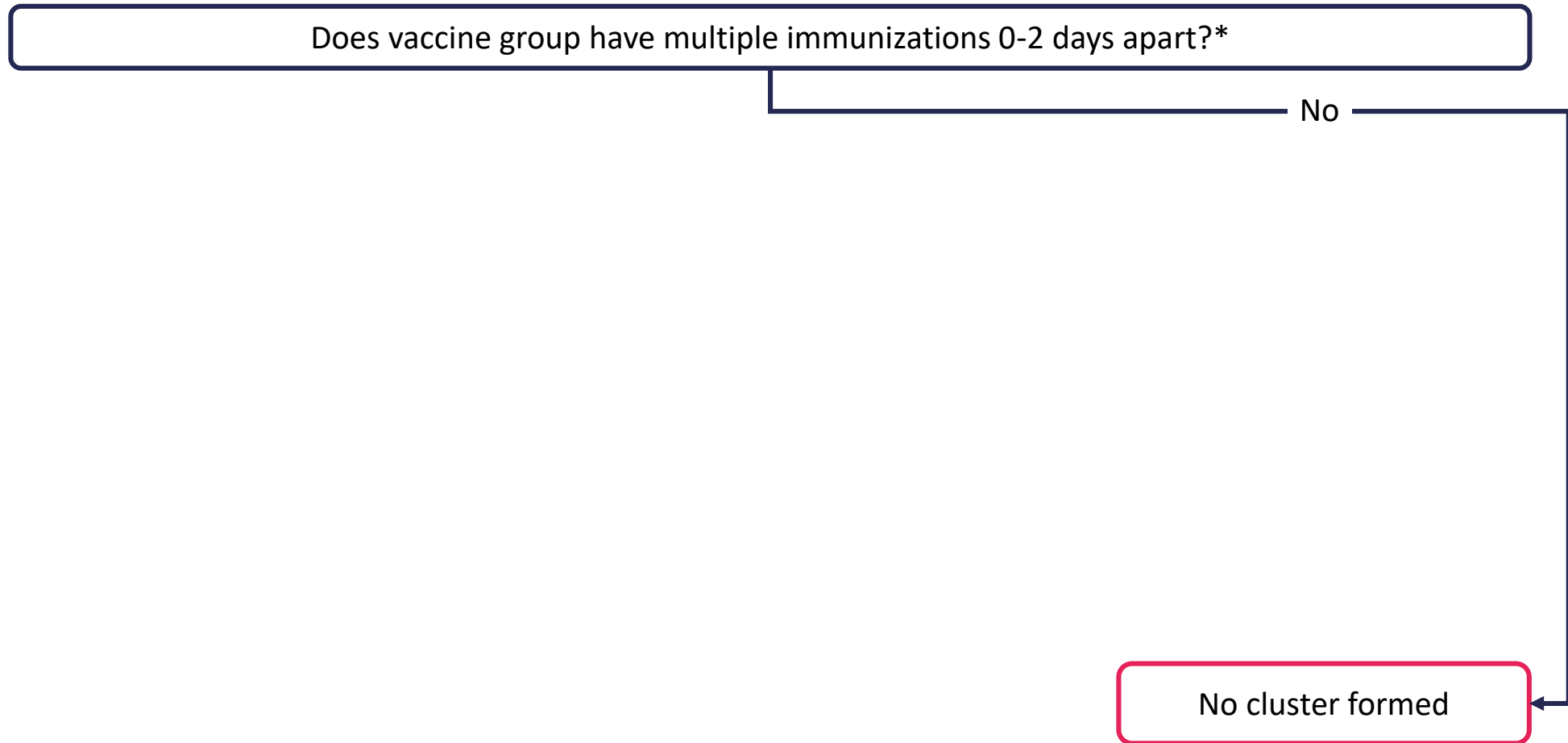
*At the patient level; each vaccine group is evaluated individually*

Does vaccine group have multiple immunizations 0-2 days apart?\*

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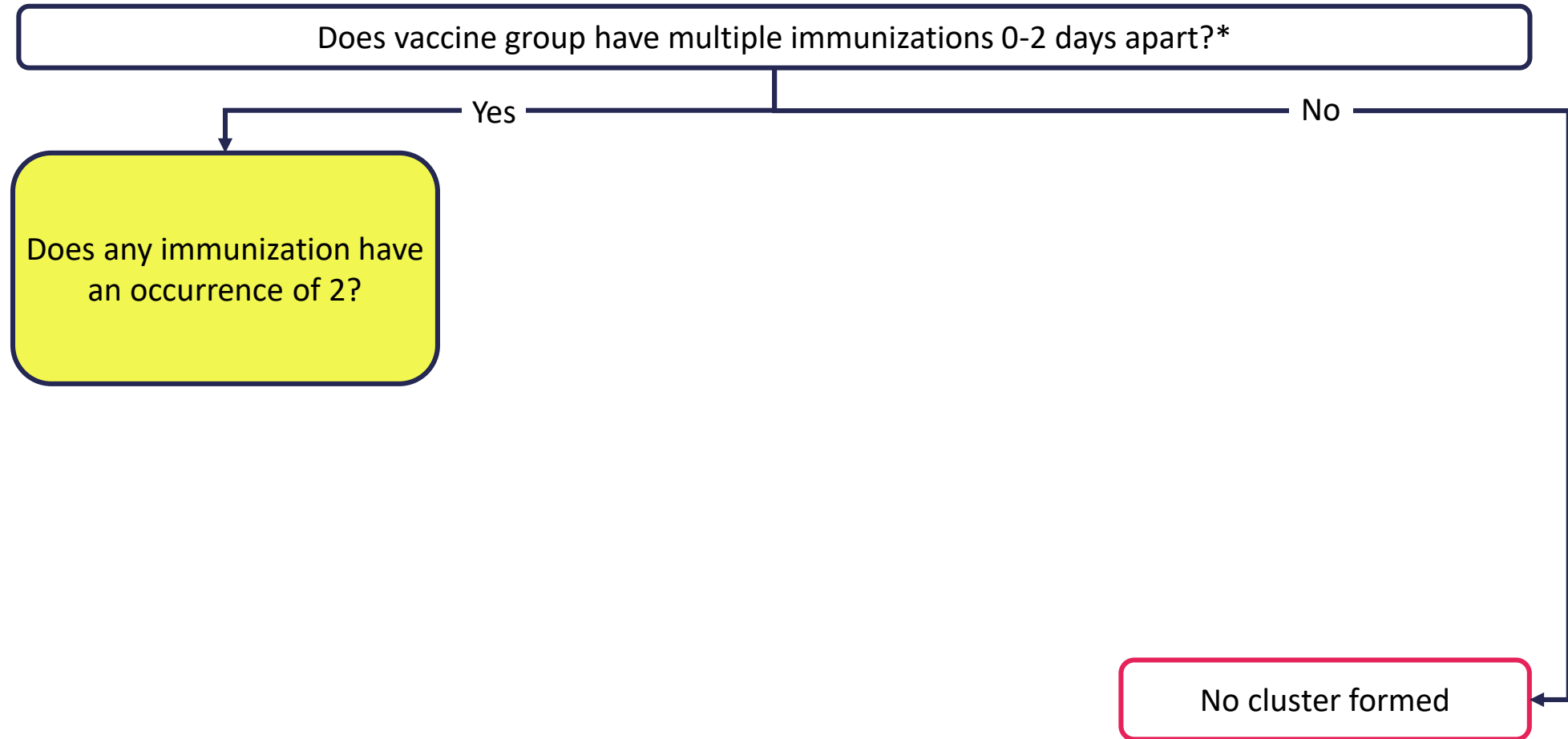
Definition: A cluster is a group of potential immunization duplicates identified for duplication that send to immunization deduplication program for clean up.

\*AIRA Modeling of Immunization Registry Operations Workgroup (eds). Vaccination level deduplication in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December, 2006.

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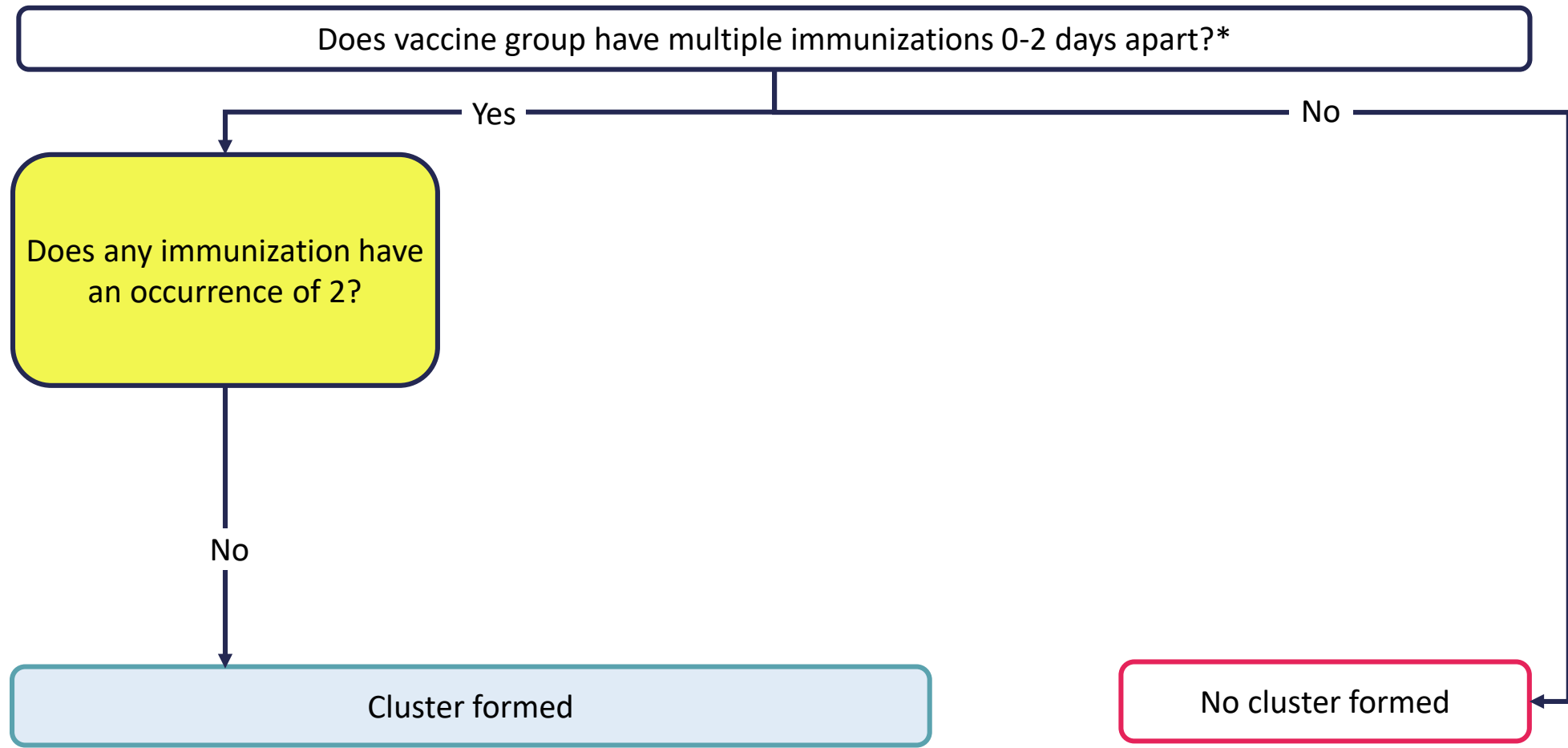
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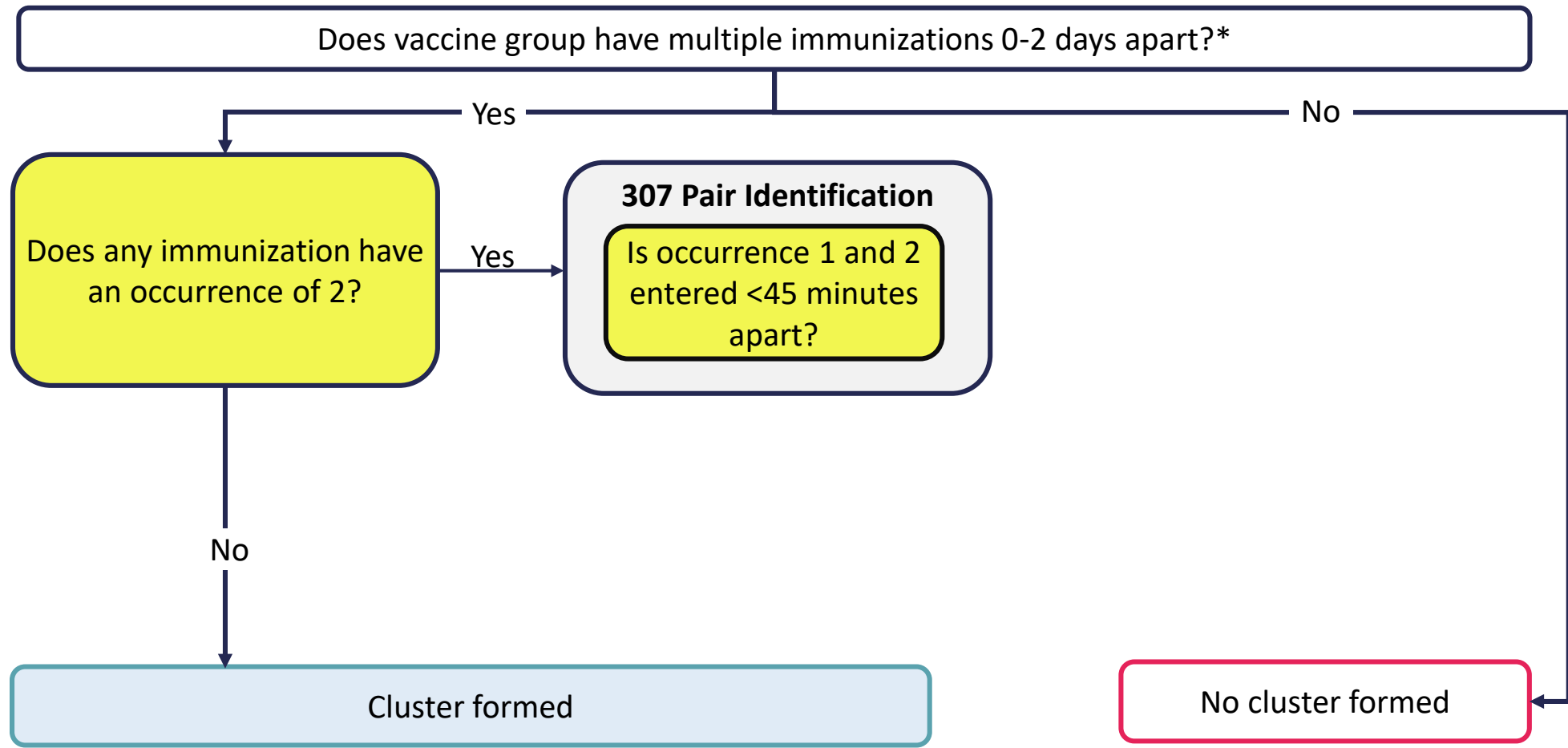
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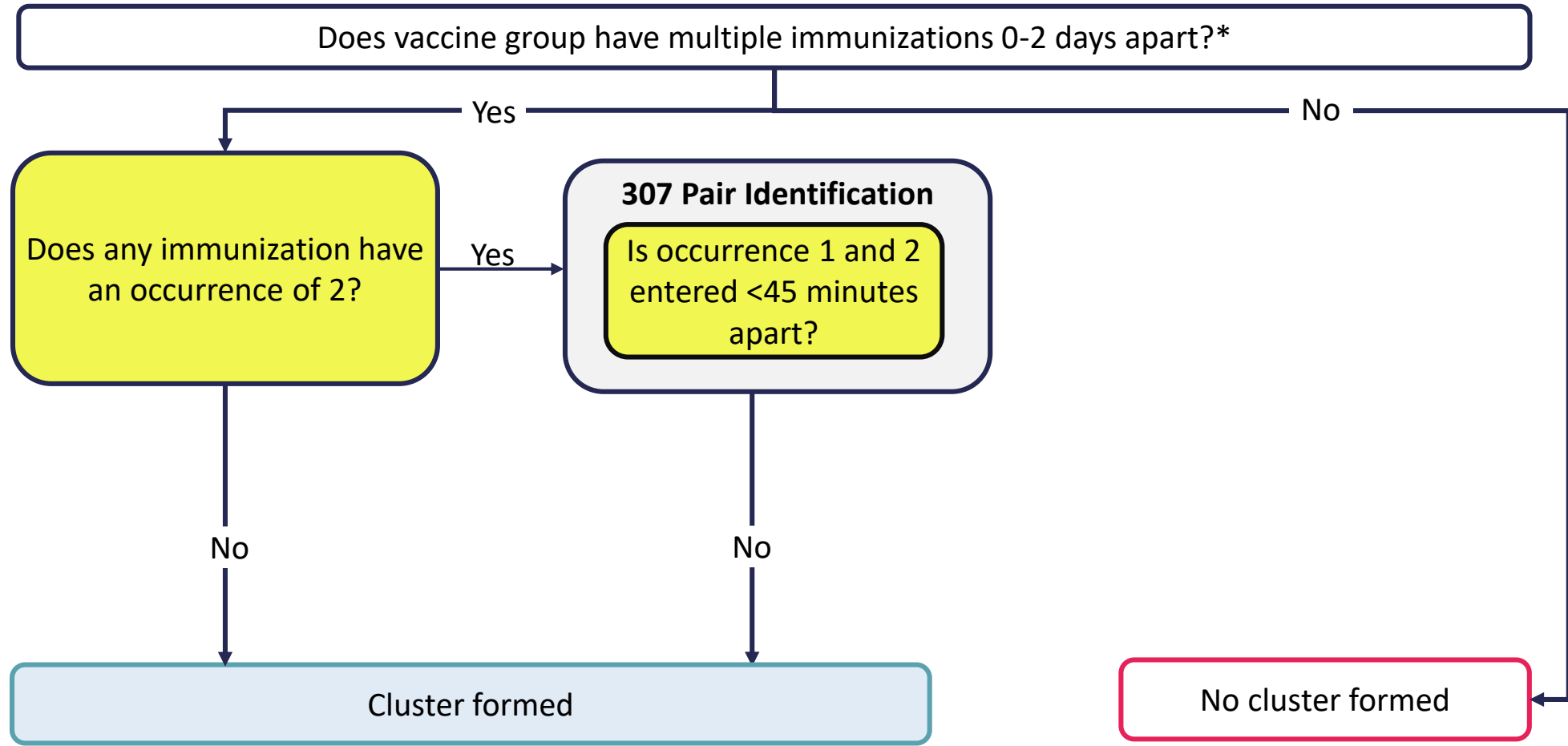
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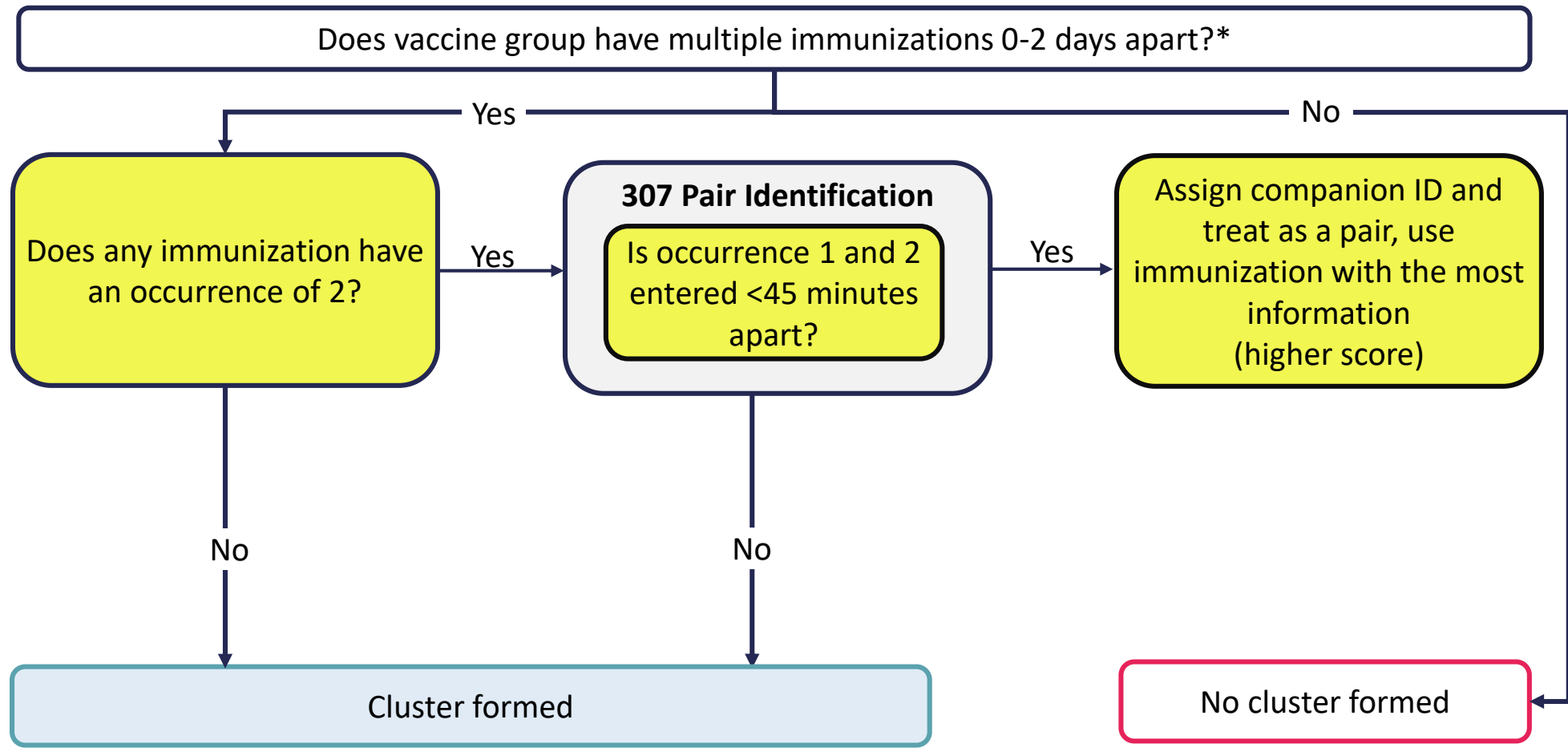
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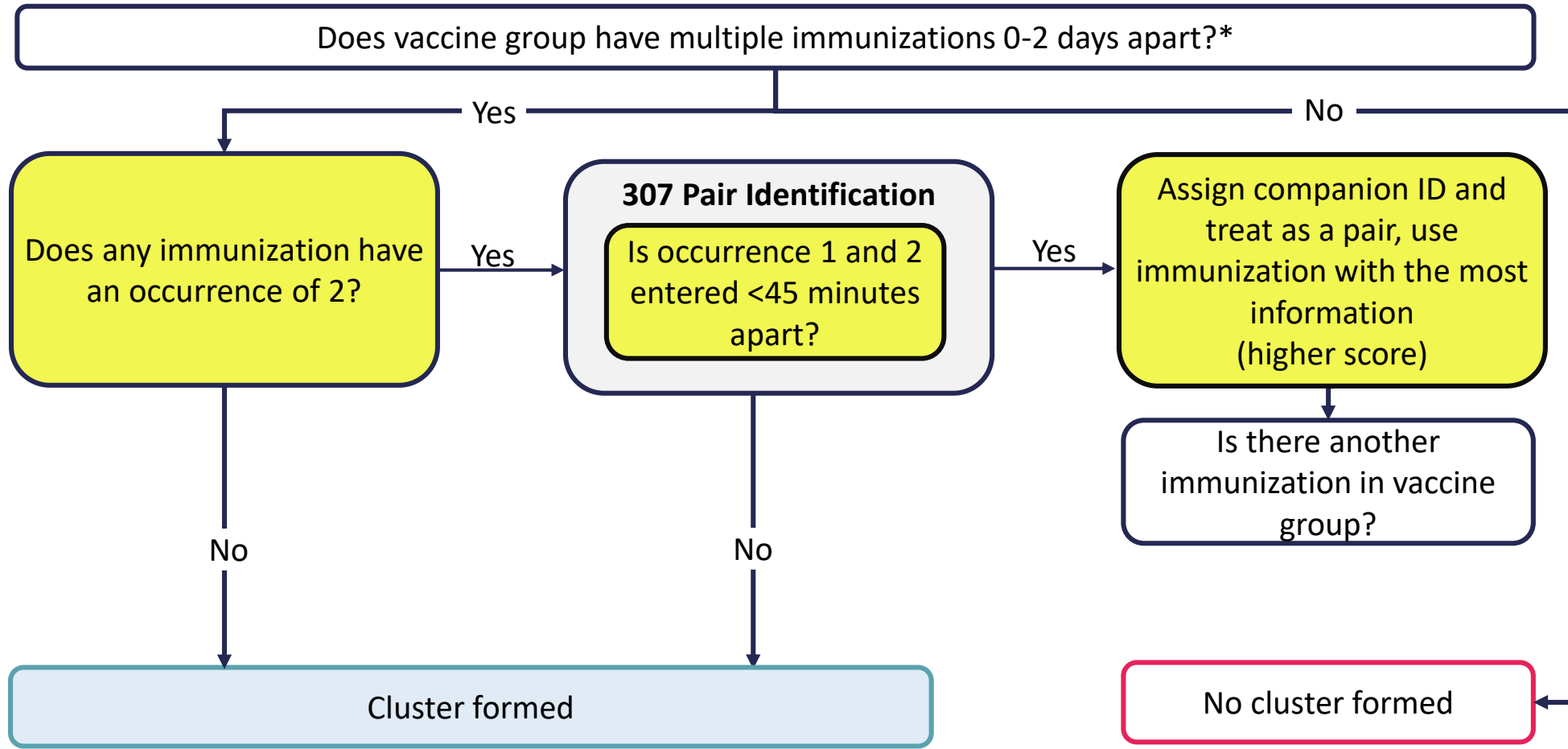
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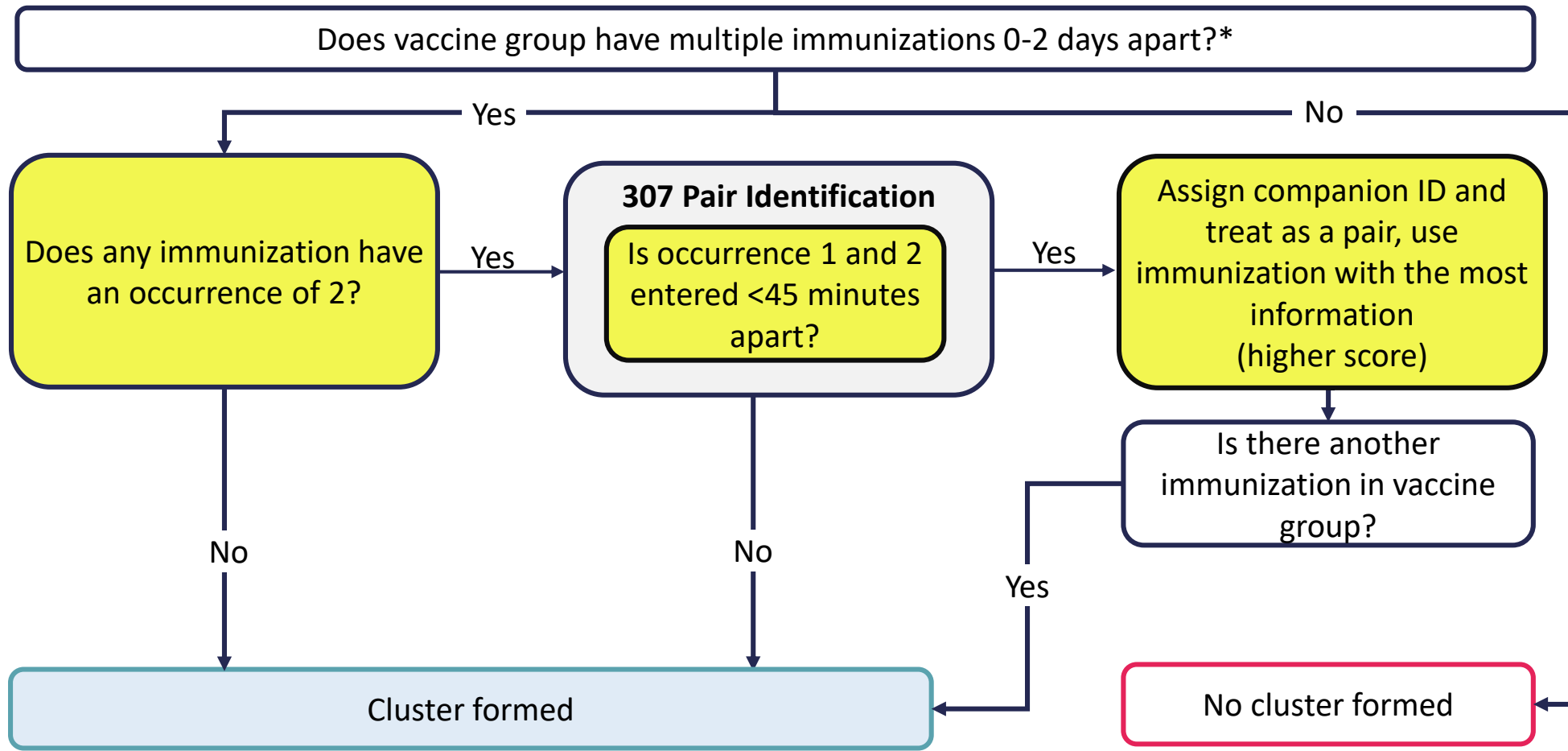
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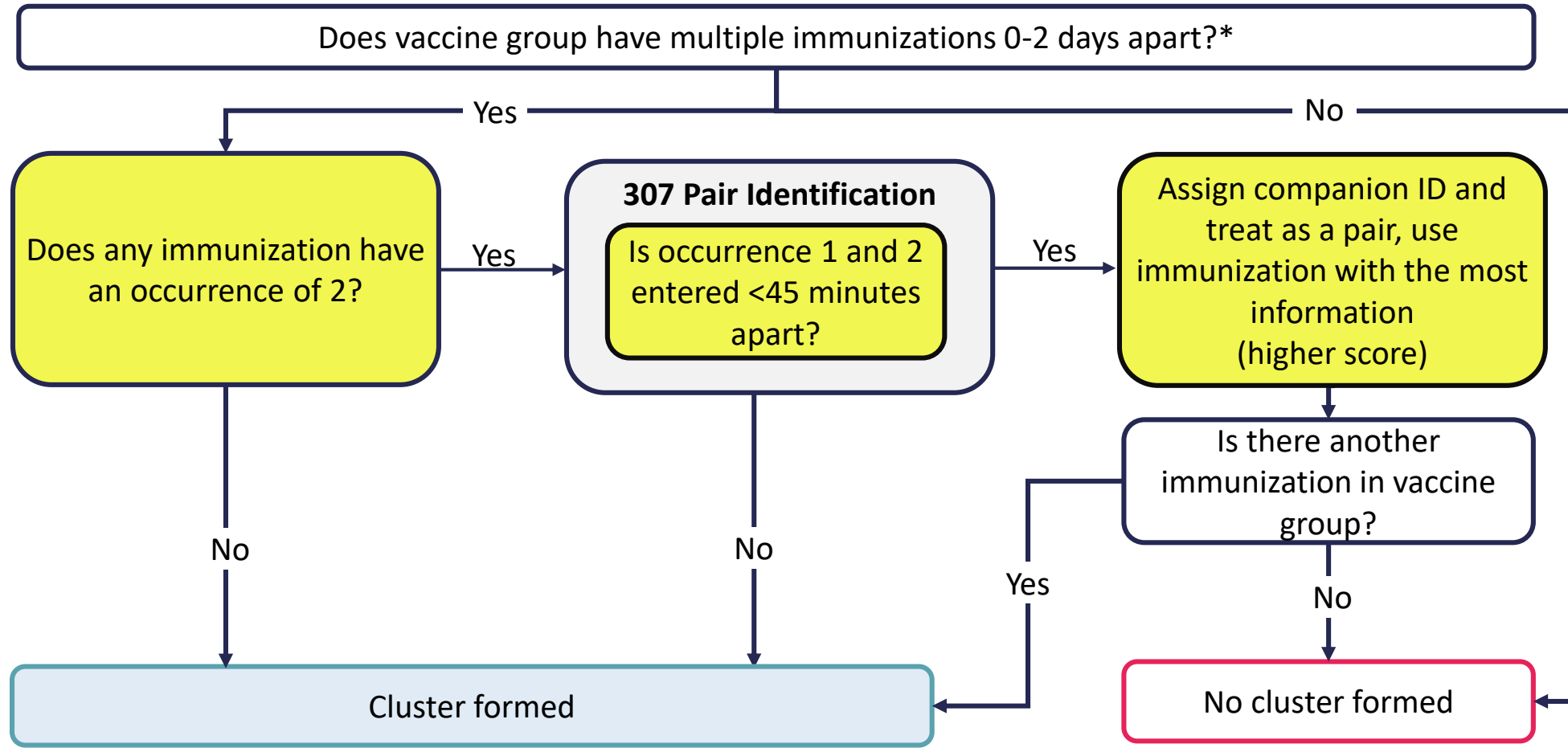
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# Immunization De-duplication: Evaluation

## 2. Evaluation Phase

*Each immunization event is scored individually*

Initial Score	
Combo product	100
MMR (CVX 03)	50
All other product	10

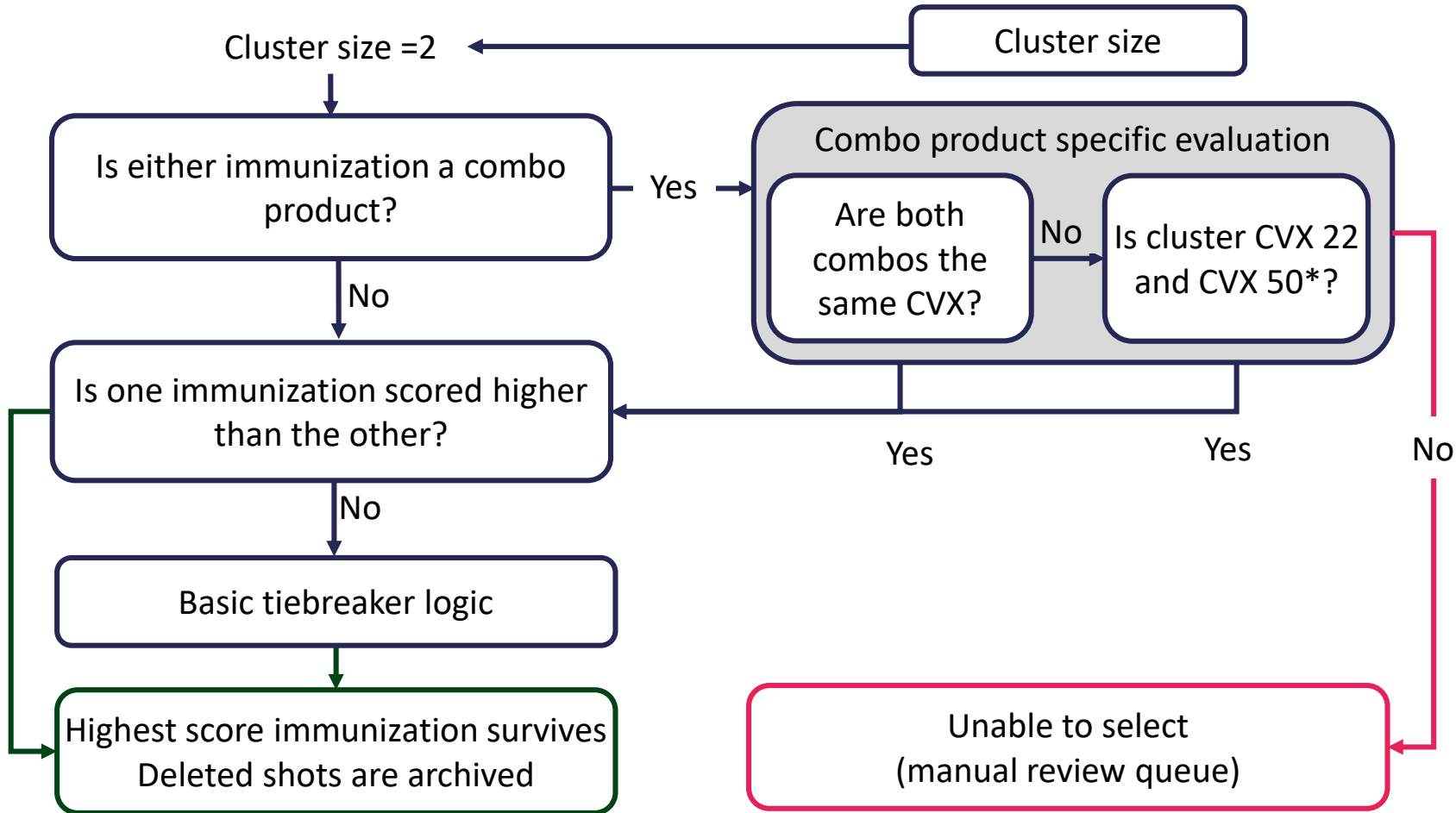


Additional Scoring Algorithm	
Immunization is vaccinator	+2
Immunization date is before license date or after end date	-5
Product lot number exists	+2
Manufacturer exists	+1
Edited by CIR staff	+2
VFC eligibility code is specified	+1
Facility code is a vital record facility	+500
Immunization event has a companion ID	+5

# Immunization De-duplication: Resolution

## 3. Resolution Phase

Each cluster is evaluated to determine surviving immunizations

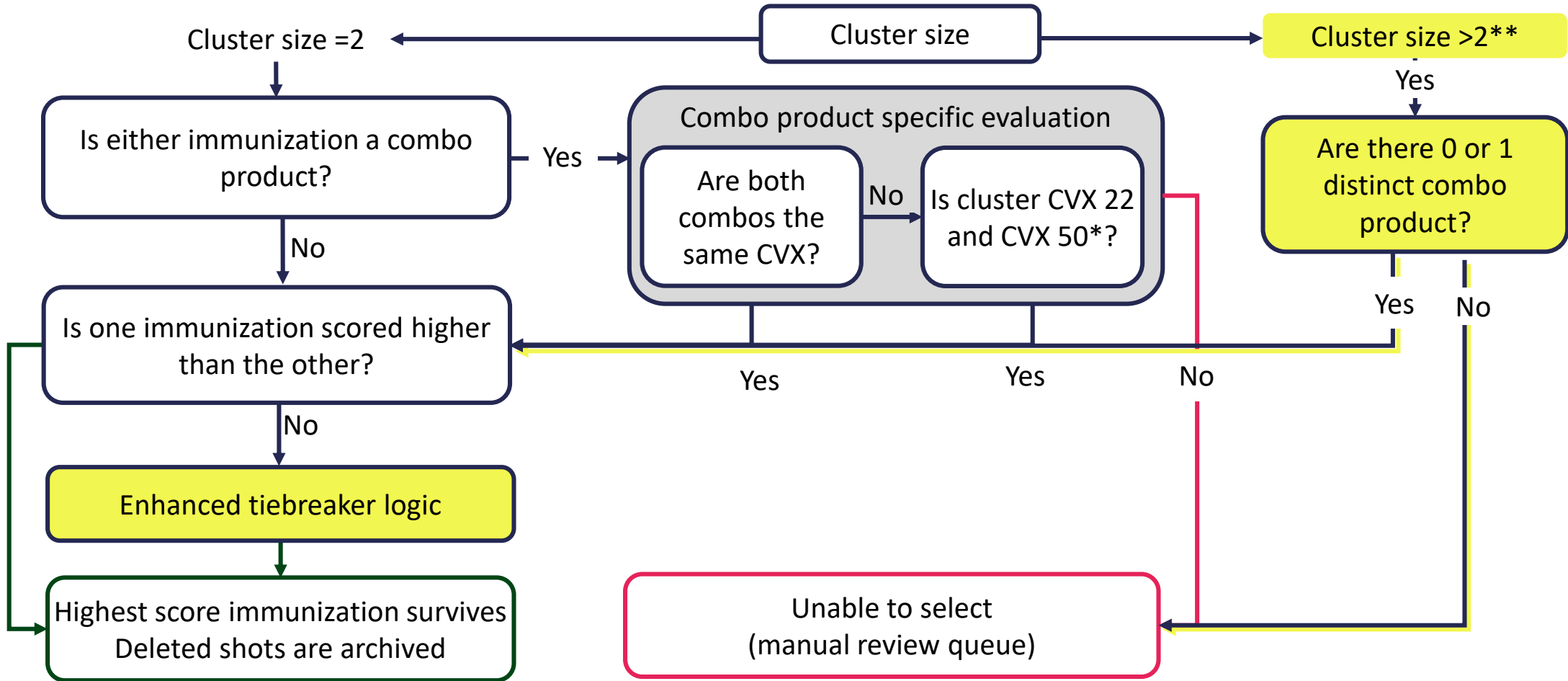


\* CVX 22 is DTaP-Hib; CVX 50 is DTP-Hib. They are combo products contain components in the same groups.

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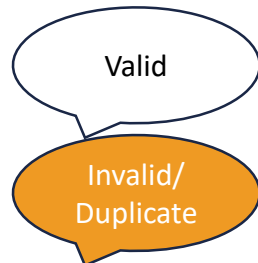
\* CVX 22 is DTaP-Hib; CVX 50 is DTP-Hib. They are combo products contain components in the same groups.

\*\*During the modification, CIR also enhanced the program to handle cluster sizes > 2.

# Before Immunization De-duplication: Multiple Shots on the Same Date in Online Registry

Immunization History				
Event	1	2	3	Next Due
<b>Influenza</b> 2 Event/s	09/30/2024 Influenza-IIV4 IM, Presrv-free(6-35mos) 8m 4w	09/30/2024 Influenza NOS 8m 4w		Due now Influenza
<b>COVID-19</b> 0 Event/s				Due now COVID-19, mRNA
<b>Meningococcal B</b> 0 Event/s				Not recommended
<b>Orthopoxvirus</b> 0 Event/s				
<b>RSV</b> 2 Event/s	10/30/2024 RSV-mAb nirsevimab 100mg (BEYFORTUS)<25m 9m 4w	10/30/2024 RSV-mAb nirsevimab 100mg (BEYFORTUS)<25m 9m 4w		Recommended for high risk groups

## Footnotes



1 : The vaccine administered is outside of the routine series.

2 : The shot was a duplicate given on the same day.

# After Immunization De-duplication: Validating Two Concurrent CVX 307 in Online Registry

Immunization History				
Event	1	2	3	Next Due
<b>Influenza</b> 2 Event/s	09/30/2024 Influenza-IIV4 IM, Presrv-free(6-35mos) 8m 4w			Due now Influenza
<b>COVID-19</b> 0 Event/s				Due now COVID-19, mRNA
<b>Meningococcal B</b> 0 Event/s				Not recommended
<b>Orthopoxvirus</b> 0 Event/s				
<b>RSV</b> 2 Event/s	10/30/2024 ① RSV-mAb nirsevimab 100mg (BEYFORTUS)<25m 9m 4w	10/30/2024 ① RSV-mAb nirsevimab 100mg (BEYFORTUS)<25m 9m 4w		Recommended for high risk groups

## Footnotes

Valid

1 : The vaccine administered is outside of the routine series.

# Results

# Results (1): Inbound HL7 Messages of CVX 307 in MTS

- With the business rule changes, between November 2023 and March 2025, MTS received 48,156 instances of 307 from HL7 Web Service
  - 24,397 were distinct immunizations added to the CIR
  - 813 were delete requests
  - 459 had new information to update the existing immunization
  - 22,487 were ignored and considered as duplicates

# Results (2): RSV Immunizations Deleted through Immunization De-duplication Process

- Between September 2023 and March 2025 among infants and children aged 0 – 19 months:
  - 1,474 ACIP approved RSV immunizations of any CVX\* were deleted
    - 1,055 (72%) CVX 307 immunizations deleted
- As a result, 106 surviving CVX 307 pairs retained in 105 patient records among infants and children aged 8 – 19 months
  - 4.5 ± (11) minute mean (standard deviation) time between two CVX 307 entries
  - 97% (103) had the same score
  - 92% (97) had the same lot number

\*RSV CVXs included all ACIP approved RSV products for different age groups: 303 (Arexvy), 304 (RSV, unspecified), 305 (Abrysvo), 306 (BEYFORTUS, 50 mg), 307 (BEYFORTUS, 100 mg), 314 (RSV vaccine, unspecified), 315 (RSV monoclonal antibody, unspecified), and 326 (mRESVIA). <https://www.cdc.gov/iis/code-sets>

# Special Consideration for Data Quality

# Special Consideration for Data Quality

- CIR does not capture medical conditions to identify high-risk population due to certain medical conditions
- CIR is unable to distinguish between the same CVX 307 submissions with <45 minutes apart but truly a re-submission of the same shot
- Some providers are reporting palivizumab (SYNAGIS, CVX 93, another RSV monoclonal antibody prior to the introduction of nirsevimab) for nirsevimab
  - Both palivizumab and nirsevimab reported on the same immunization date
  - Some palivizumab doses had lot numbers of nirsevimab
  - They would not form a cluster in immunization deduplication since nirsevimab is in the 'RSV' group but palivizumab is in 'Other' group (not a ACIP recommended product to complete RSV series)

# Conclusions

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- Immunization-level de-duplication is an essential IIS activity that requires identification and selection of a single immunization event among duplicate immunization events
- The ACIP recommendation of two 100 mg identical RSV shots on the same day was new to all IIS jurisdictions
- CIR created a high-performance solution using both front-end and back-end solutions to store and identify two immunization shots for the same immunization event
- Although the high-risk infant population is small, this new approach ensures that patients have accurate immunization records in the IIS

# Thank you!

- **NYC DOHMH Bureau of Immunization**

  - Alexa Riggs

  - Alexandra Ternier

  - Nilram Halat

  - Conner Jackson

  - Bindy Crouch

- **AIRA 2025 Meeting Committees**

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