
2024 VIZIENT CONNECTIONS SUMMIT
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Froedtert, Mayo and Yale Unite to Renovate Product Recall Ecosystem

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Learning Objectives

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- Discuss gaps in the current product recall management system.
- Explain the value of integrating the Voice of the Customer as a standard.

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How does a day in the life of a Recall turn into 45 days?

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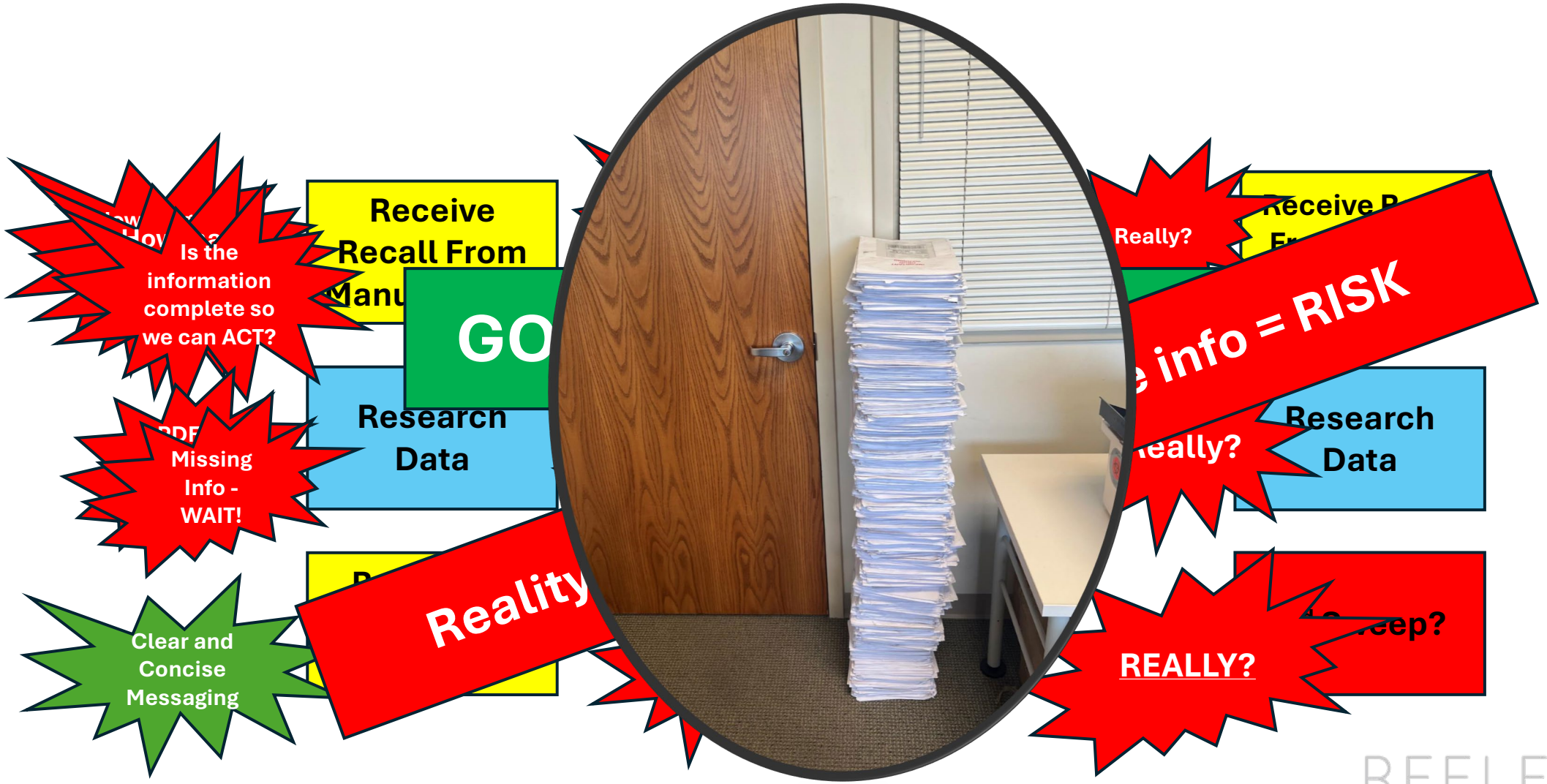

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General Recall Questions?

What are challenges with Recall Management?

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Health System (HS's) Customers

Patient Risk Factors

- Unpredictable Delivery Systems (paper, email, portals) - delay action
    - Slow, recalls received by US Mail - delay action
- No Standard Recall Format
    - All must be researched - delay action
    - HS require specific information to execute a recall, which is rarely provided - delay action

Management Required

- Multiple of the same notification sent by vendor, distributors, and FDA create confusion and rework (average 4)
- 3rd party companies hired by MFG's produce inconsistent messaging, delivery delays, and response hardship
- Vendor portals: Health Systems can not track and document notices. They do not satisfy HS's regulatory requirements
- HS's require notices to arrive to a recall administrator for system wide messaging and concise action
- Notifications are received as PDF. HS's require word or excel to properly break down the notification to cross to inventory

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- Must subscribe to management platforms to ensure receipt of all recalls
- Labor from sweeping and returning product is not recouped
- Credit for recalls are not easily tracked
- At times, no credit nor replacement product is offered
- Forced to purchase alternate product at HS's expense

Manufacturers (MFG's)

Patient Risk Factors

- Unpredictable Delivery Systems delay action

    Paper mailings:
    - average 34 days for paper to reach a recall coordinator
    - Delivered/addressed to the wrong department and/or staff
    - Typically sent location specific and rarely organized by HS

    Emails:
    - vendors do not have the email address of recall administrators – they do not know how to contact them

    Vendor Portals:
    - are inaccessible to health systems and do not satisfy HS's regulatory requirements
- Acknowledgements are difficult to track
- Notifications are sent as PDF, HS's require word or excel to properly break down the notification to cross to inventory

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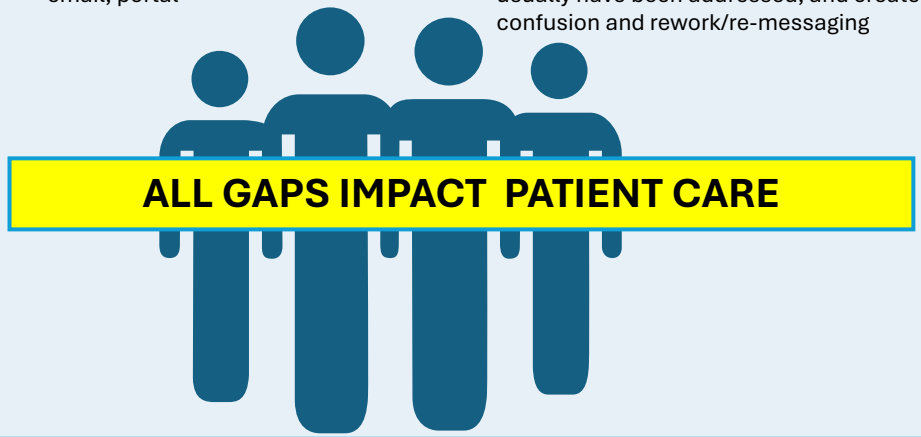
- Paper mailings average $1M per recall
- Pay 3rd party 'bounty hunters' hired to 'manage' recall responses to satisfy FDA requirements, create hardship on HS's and cost to MFG's
- Portals were created to streamline recall notification and responses; however, they make it impossible for HS's to manage recalls across multiple locations due to access constraints and algorithms

Recall Management Platforms

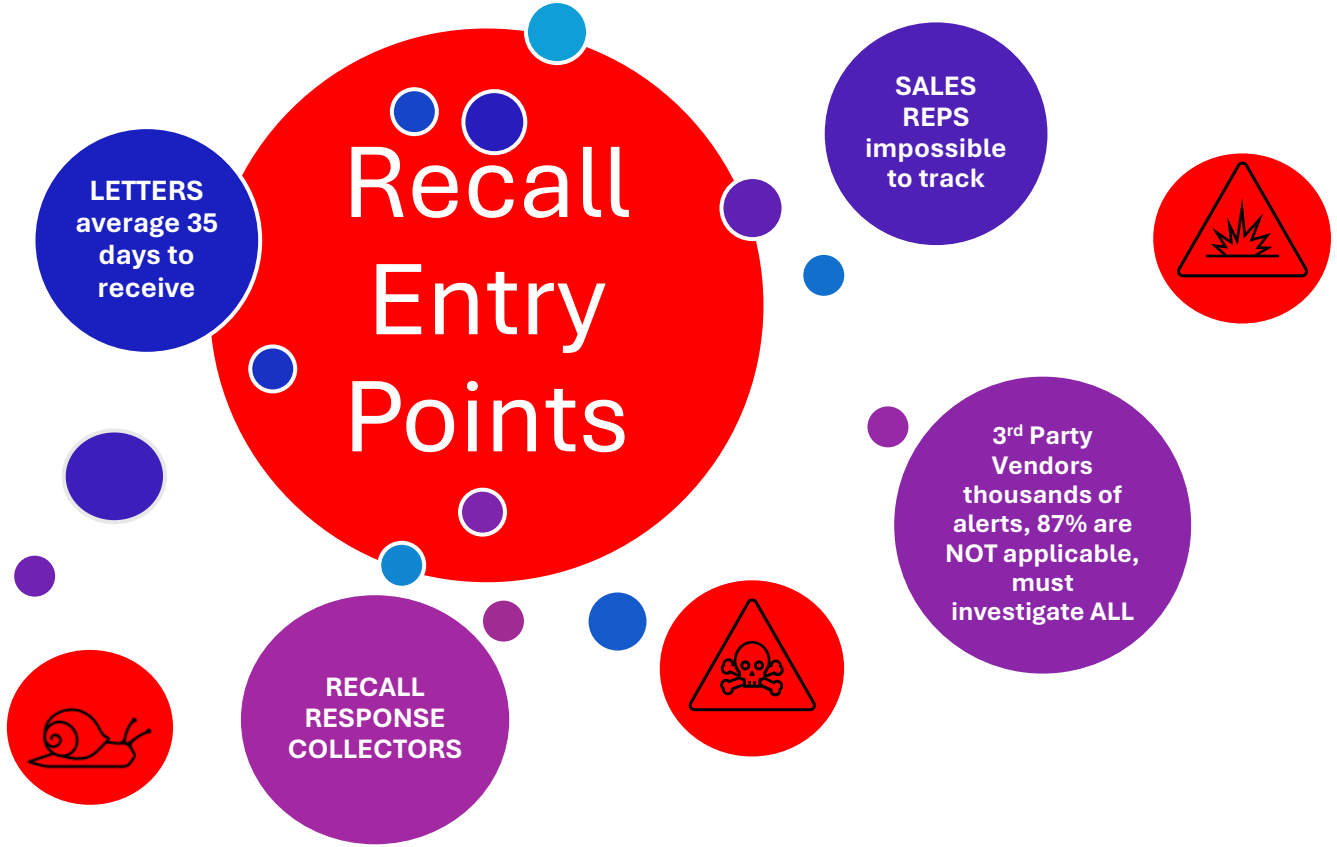
- HS's must pay for membership
- 87% of recalls events are not applicable to the HS member
- Manufacturers and distributors do not work directly with the platform
    - creating communication gaps and redundant notifications
    - HS's can not respond directly to mfg's and distributors through this membership. They must reply direct, sometime to both, creating rework
- Multiple sources of truth, notification are pulled from
    - regulatory agencies
    - Health system customers provide the recall once received via mail, email, portal

FDA

- Recall have not been updated since year.....?
- Digital communication qualification are vague
- Regulatory requirements are vague
- Cannot dictate solutions
- Cannot provide funding
- Auditors randomly reach out to HS to audit mfg recalls. They are not in standard format, they are vague we must ask clarifying questions, these requests come in frequently eroding bandwidth
- No transparency to completing recalls
- FDA classifications, the umbrella terms, can create panic ie bulletins, IFU's, etc. are classified 'recall'
- Typically, there is a delay in receiving the FDA recall notifications, when broadcast, they usually have been addressed, and create confusion and rework/re-messaging



What are some recall Communication Methods?



Using Electronic Means to Distribute Certain Pr...
Guidance for Industry - Using Electronic Means to Distribute Certain Product Information

www.fda.gov

[Using Electronic Means to Distribute Certain Product Information | FDA]

What is the ‘Recall Management Interest Group’?

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GOALS

Nationwide Best Practices

Recall Standardization

Speed to Safety

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Who is RMIG?

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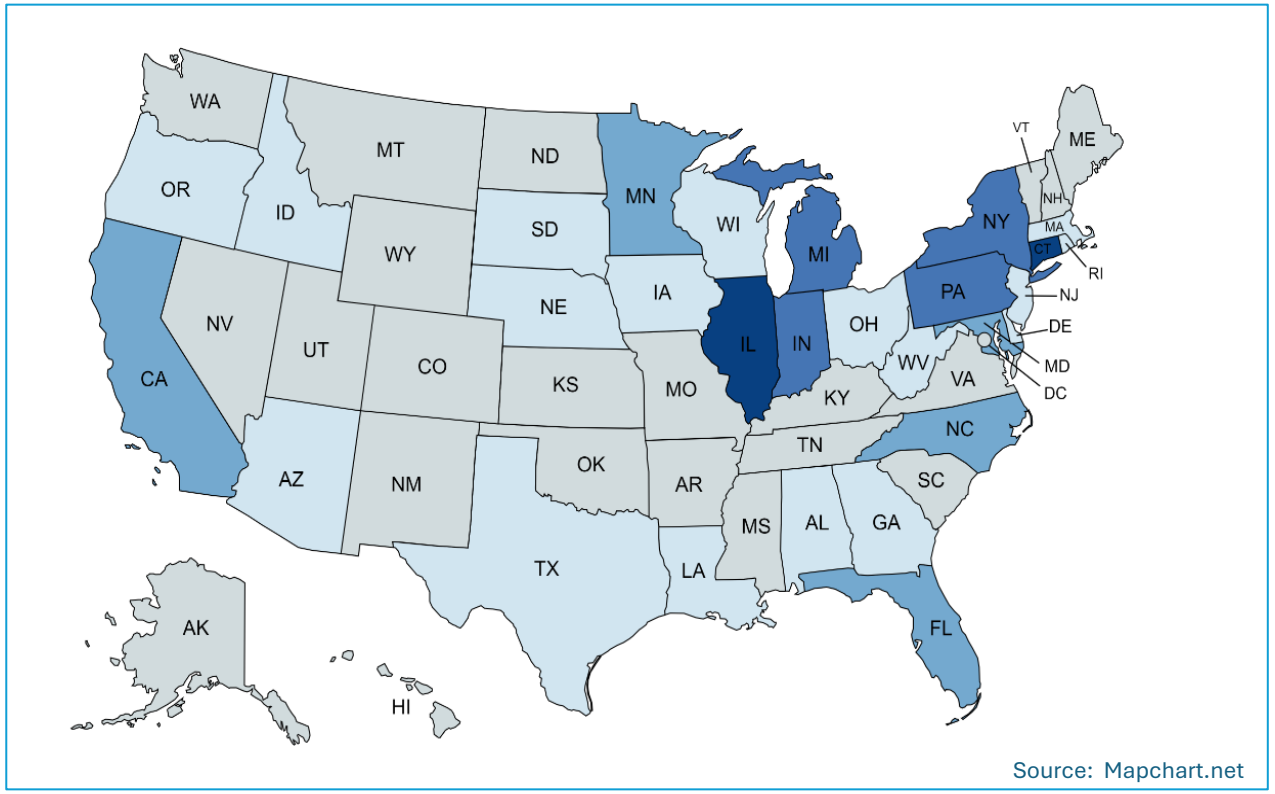
How Many RMIG Organizations are in Each State?



Source: Mapchart.net

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What are some best practices?

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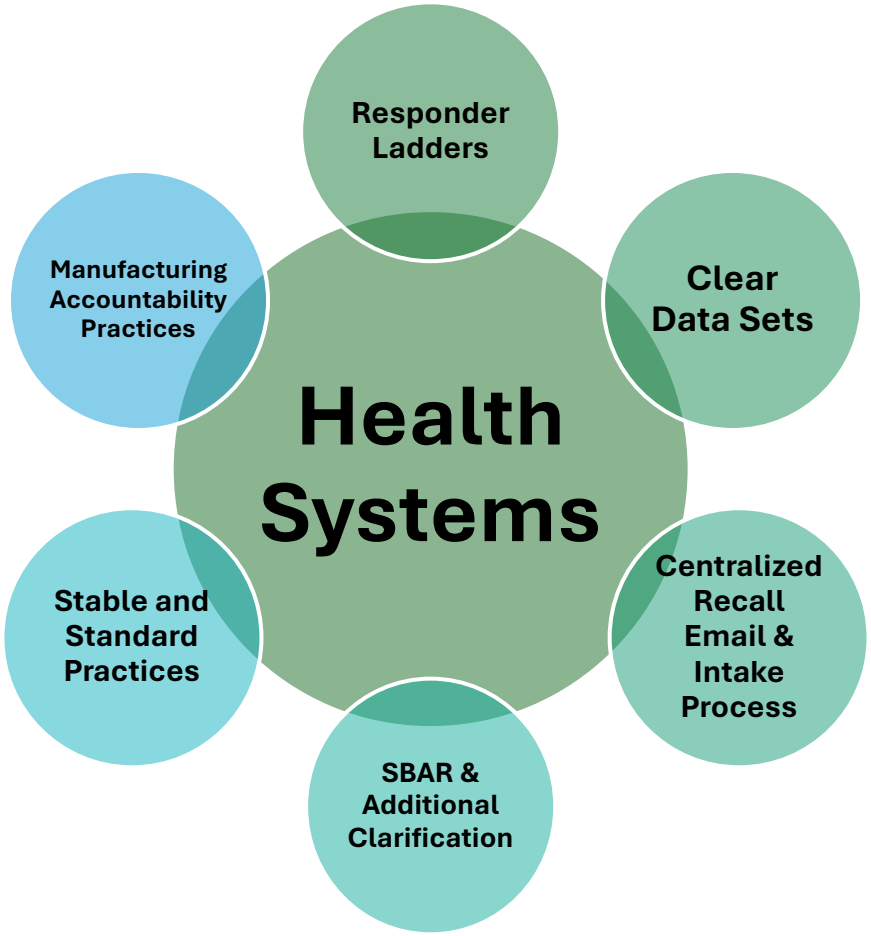

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What are the big pieces RMIG is working on?

How can you be involved?

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Recall Management Interest Group

health care systems uniting to create best practices and mitigation strategies to reduce risks and pain points imbedded within the current national recall ecosystem

Charter

- Bringing standardization to the product recall communication process

Goals:

- To manage a recall effectively and efficiently from a supplier in the timeliest way, minimizing days at risk for our patients.
- To develop a standardized list of
- information needed from suppliers for providers to efficiently process a recall.
- To have all the information needed to manage a recall successfully and effectively in a timely manner.
- Identify collaborative recall initiatives

Accomplishments

- ✓ A live "best practice" network to provide real time crosschecks or assistance with product events
- ✓ Developed a shared template for suppliers
- ✓ Determined and shared the vital pieces of information to execute a recall notice
- ✓ Abstract Submissions
- ✓ Feeder group to multiple FDA initiatives/pilots/studies representing the voice of the provider

What to Expect

Regular Meetings

- Team Discussions
- Guest speakers
  - FDA
  - Manufacturers
  - Industry Experts

Share our message

- Share Template
- Join professional groups

Working sessions

- Brainstorming Solutions
- Portals
- 3rd party inquiries
- Inventory centers
- Recall communication

Free – No Fees

NO HIDDEN AGENDA: simply sharing pain points, ideas for improvement, and best practices

NO ASSOCIATION OR ALLIANCE WITH manufacturers, professional organizations, GPO's or 3rd party recall platforms

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Lessons Learned

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- Pain points of recall management are an undercurrent in every health care system
- There are documented gaps in the current recall management ecosystem
- Partnership is essential between providers, suppliers, and the FDA
- It is essential to integrate the Voice of the Customer (Health Care Systems) into all national recall standards
- You are NOT ALONE
  - Small processes have great impact
- Calling all Health Care Systems to Collaborate
  - Regardless of individual practices, size, etc., we all have a voice in positive change

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Key Takeaways

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- Recalls are not a bad thing – they keep patients safe
- Speed to Safety is critical to keep our patients safe
- Email Recall Notifications are critical for Speed to Safety
- Urge Suppliers to adopt Recall Standards
- Uniting through RMIG

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Questions?

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