

# FDA Working Group Update

Claudia Manzo



**ANNUAL MEETING**

**COLLABORATE, STANDARDIZE,  
INNOVATE TO MODERNIZE REMS**

MARCH 11-12, 2026 • WESTIN  
ARLINGTON, VIRGINIA



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# Marketing & Communications Working Group Update



ASSOCIATION  
HEADQUARTERS

March 2026



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# AGENDA

- Glossary of Terms
- Year-over-Year Marketing Metrics: 2024 vs 2025
- Engagement Drivers
- Member Retention & Recruitment
- Future Marketing Recommendations



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## **Engagement Rate**

Metric that tracks how actively involved your audience at large is with your content your audience at large. Engagement rate metrics can vary by social channel but typically include reactions, clicks, comments, and shares. Certain metrics have more weight than others. For example, a comment has a higher value than a reaction because of the additional effort of a comment by the user.

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## **Page Engagement Rate**

The number of times people clicked, liked, commented, shared, or performed any time of click on any content from your Page, as a percentage of the people who saw them.

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## **Post Engagement Rate**

The number of times people clicked, liked, commented, or shared content from your Page, as a percentage of the people who saw them.

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## **Post Impressions**

The number of times content is displayed on a user's feed, no matter if it was clicked or not.

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## **Page Impressions**

The number of times our Pages' posts were displayed on users screens.



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# Year-over-Year Marketing Metrics: 2024 vs 2025



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# 2024 vs 2025: LinkedIn



**PAGE FOLLOWERS**  
(2025)

**1.2k**

**+33%\***

**PAGE IMPRESSIONS**  
(2025)

**61k**

**-36%\***

**AVG PAGE ENGAGEMENT**  
**RATE (2025)**

**9k**

**+20%\***

**AVG POST ENGAGEMENT**  
**RATE (2025)**

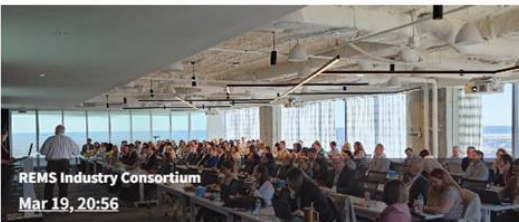
**11%**

**+3%\***

\*Metric change from 2024

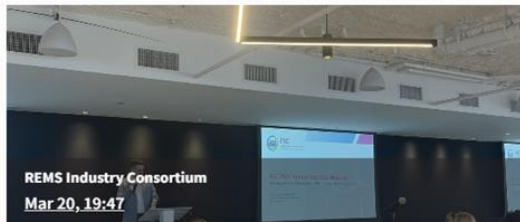
## TOP 3 PERFORMING LINKEDIN POSTS IN 2025 BY ENGAGEMENT RATE

**in** Top posts



🔥 And with that Day 1 of the #RICAnnualMeeting2025 comes to a close! Filled with learning, valuable networking, and having fun, today was a great way to kick off this year's annual meeting! Thank you Claudia Manzo and Cynthia LaCivita for your insightful opening keynote address. We look forward to seeing you all

**127.2%** engagement rate



👏 That's a wrap for the #RICAnnualMeeting2025! Day 2 of the annual meeting was filled with sharing best practices, building connections, and fidget toys! We are pleased to have welcomed Dr. Sarah Nikiforow as our closing keynote speaker for the 2nd year in a row. Thank you to all attendees for making this

**98.88%** engagement rate



The RIC team had the pleasure of attending an informative bi-annual gathering at the FDA to gain exclusive insight and valuable updates for future of drug safety industry. Check out the RIC FDA news and resources now: <https://ow.ly/u5hi50vUEJy>

**32.26%** engagement rate

# 2024 vs 2025: Email

  
**Campaign Monitor**  
yourmembership<sup>™</sup>  
by communitybrands

EMAILS (2024)

**55**

**+57.1%\***

AVG OPEN RATE (2025)

**40%**

**+8%\***

AVG CLICK THROUGH RATE (CTR) (2025)

**21%**

**+50%\***


BOUNCE RATE (2025)

**1.2%**

**-0.1%\***

\*Metric change from 2024

## TOP PERFORMING EMAIL OF 2025 BY CLICK RATE



**Take Your Pharmaceutical Plans to the Next Level**

A RIC membership benefits all companies working to advance patient safety. It's not just for those with REMS programs. Here's why:

You are an essential participant in moving the pharmaceutical industry forward and bolstering patient safety and positive outcomes. Through research, innovation, and experience, pharma professionals contribute to advancing best practices in the development and regulation of new drugs and biologics.

As a RIC Member, you can generate cost savings by reducing the time to market through shared best practices across organizations (including data compliance, reporting standards and innovation).

Only through RIC membership can you become part of the collective industry voice that works directly with the FDA to find ways to cut down the approval time for REMS innovation.

[Join RIC Now](#)

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**Updates From the FDA**

Leadership from the REMS Industry Consortium recently met with the FDA to discuss a number of important items:

- Processes for addressing comments during the REMS program submission
- Challenges related to REMS Assessment Reports and their timing
- Streamlined communications
- PDFA Updates
- The possibility of a REMS Application Orientation Meeting
- Considerations in releasing a REMS
- The REMS Logic Model

**Oct. 30, 2025**

**OPENS: 55.8%**

**CTR: 51.2%**

**Aug. 7, 2025**

**OPENS: 53.4%**

**CTR: 39.7%**



**REMS Education Only Available to RIC Members**

Have you heard? The RIC Education and Certification Working Group recently completed Module 1.3 on FDA Negotiations of the REMS training program. The first three modules are now available and offer essential guidance for designing a REMS program, coordinating internal collaborations, and working with the FDA on approvals.

Some key highlights of the modules include:

- **Module 1.1: REMS Design & Planning:** seeks to build an understanding of the factors in FDA Decision Making when requiring a REMS, the elements of a REMS Program, and the Elements to Assure Safe Use (ETASU) in designing a REMS Program.
- **Module 1.2: Internal Collaborations:** aimed at providing the participant with an understanding of the internal collaborations needed to design and plan a REMS Program, including the role of the Point of Contact and the REMS Oversight Committee.
- **Module 1.3: FDA Negotiations:** providing the participant with an understanding of the process by which a REMS Program comes into being, and what to expect from the FDA, and when, in designing a REMS Program for New Drug Applications, Biologic License Applications, and New Molecular Entity Applications.

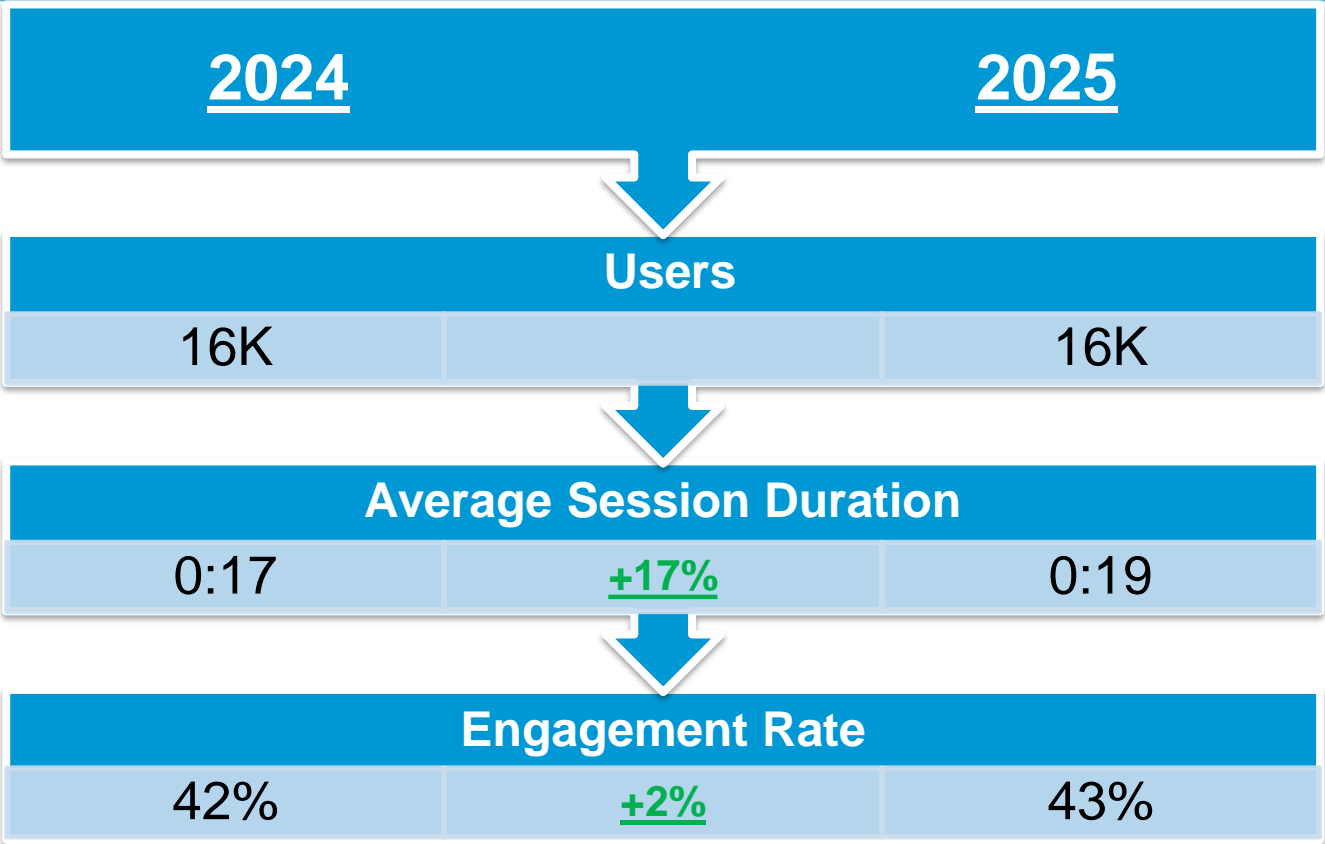
Our education modules are exclusive to RIC membership and can be found on the member portal's LMS the resource. Inside you'll be able to search for content and tools that you will need for several stages of REMS.

[Access Now](#)

What Do Others Gain from RIC Membership?



# 2024 vs 2025: GOOGLE ANALYTICS INSIGHTS





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# Engagement Drivers



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# Top Engagement Drivers

## LinkedIn:

- Industry Partner Spotlights
- Photos highlighting RIC members (WDSC, FDA, etc.)
- Member Spotlights
- RIC 2026 Annual Meeting pre-event promotional content and in-person photos of the 2025 meeting

## Email:

- RIC Newsletter
- RIC Working Group Highlights / Promotions
- RIC Learning Management System Module 1.1 - 1.3
- RIC Webinar Content



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# Member Retention & Recruitment



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# Member Retention and Recruitment

- Annual Marketing Campaign: A 6-month membership marketing campaign distributed through YM and LinkedIn. It supported the following results in 2025:
  - 2 new manufacturing members
  - 4 Ex-FDA individual members
  - 5 new industry partners
- Prospects doubled from marketing email subscribers
- 1:1 interactions with sponsors and industry partners
- Present RIC value proposition at drug safety & risk management conferences
- RIC Exhibit Booth at World Drug Safety Congress
- RIC marketing asset distribution at American Drug Safety Summit
- Marketing partnership with DIA and WhySummit
- RIC Influencers (ALL OF YOU!)





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# Future Marketing Recommendations



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# Future Marketing Recommendations

- Increase brand awareness by presenting RIC value proposition at drug safety, risk management, and regulatory events. Expand RIC footprint by securing more exhibit booth opportunities
- Use the RIC Learning Management System and Webinar content as a way to generate membership leads and show retention
- Continue *2026 Annual Meeting Marketing and Communications Plan* post event to showcase key takeaways
- Market Edu/Cert Working Group's LMS modules
- Continue Industry Partner and New Member spotlights after the annual meeting
- Incorporate motion graphics into social and email and monitor engagement compared to static images
- Consider boosting membership social posts
- Track member and potential member engagement, along with new members, following marketing activities to assess their effectiveness and measure the ROI of exhibit booths at conferences through prospect review



# Innovation & Technology Work Group 2026 Annual Meeting Update

Kyle Irwin



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## 2025 Accomplishments

- Developed and conducted AI Survey. Analyzed and discussed initial results
- Provided feedback on the *FDA Draft Guidance - Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products*
- Provided updates on CodeX initiatives and highlights from other conferences/meetings



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## 2025 Accomplishments

- Worked with FDA Interactions WG to support meetings and follow-up with FDA
- Planned virtual panel discussions, but postponed due to scheduling conflicts
- Provided Annual Meeting Planning Support (2025 and 2026)
- Updated list of vendors and their capabilities



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## 2026 Priorities

### **Engagement** - Increase group engagement and participation

- Revamp schedule meeting
- Develop fall in-person event

### **Insight and Influence**

- Highlight RIC industry partner capabilities
- Develop RIC viewpoints and whitepapers on technologies topics
- Support RIC interactions with FDA
- Update AI Survey for end of 2026/beginning of 2027



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- Work Groups Meetings - **Usually the 3<sup>rd</sup> Thursday of Month 3:00 – 4:00 PM ET**
- Occasional Meetings with FDA Interactions Work Group
- Other project meetings as needed
- Contact Dan Lemyre, Pooja Mahna, or Kyle Irwin for more information



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# Education and Certification Working Group

Presented by:

Liza Rodriguez & Michele Coiro



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- 45 Current Members
- 25% Active Members



**Jazz** Pharmaceuticals.



**Johnson & Johnson**



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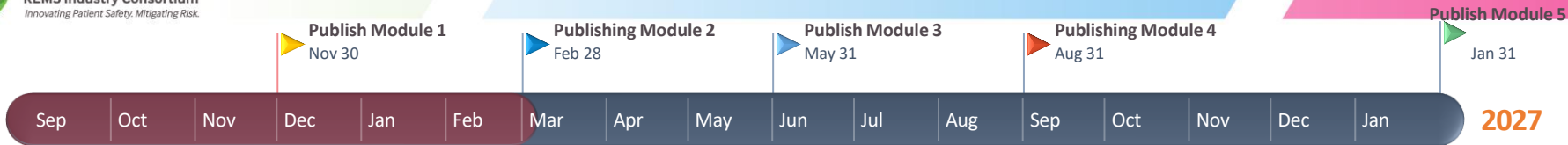
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# RIC Education & Certification Working Group Timeline 2025-2026



Today

**Module 1** Sep 1 - Oct 31

**Chapters 1.10, 1.11** Sep 9 - Oct 31

**Module 2** Nov 1 - Jan 31

**Chapters 2.1, 2.2, 2.3** Nov 1 - Nov 30

**Chapters 2.4, 2.5** Dec 1 - Dec 31

**Chapters 2.6, 2.7** Jan 1 - Jan 31

**Module 3** Feb 1 - Apr 30

**Chapters 3.1, 3.2** Feb 1 - Feb 28

**Chapters 3.3, 3.4, 3.5** Mar 1 - Mar 31

**Chapters 3.6, 3.7, 3.8** Apr 1 - Apr 30

**Module 4** May 1 - Jul 31

**Chapters 4.1, 4.2** May 1 - May 31

**Chapters 4.3, 4.4, 4.5** Jun 1 - Jun 30

**Module 5** Sep 1 - Dec 31

**Chapters 5.1, 5.2, 5.3** Sep 1 - Sep 30

**Chapters 5.4, 5.5** Oct 1 - Oct 31

**Chapters 5.6, 5.7** Nov 1 - Nov 30

**\*Chapter timelines include authoring content, reviewing, approving, recording and transcribing**

Module 1 is Published  
with 11 Chapters  
Focused on Design &  
Planning REMS

Module 2 is in progress  
with 2 Chapters  
Published

## RIC Learning Management System

### RIC REMS Education Module 1 - Design & Planning

- Module 1.1 REMS Design & Planning
- Module 1.2 Internal Collaboration
- Module 1.3 FDA Negotiations
- Module 1.4 Stakeholder Perspectives
- Module 1.5 REMS Components
- Module 1.6 REMS Submissions
- Module 1.7 Noncompliance Plan
- Module 1.8 Developing an Assessment Plan
- Module 1.9 Audit Plan
- Module 1.10 Service Provider Selection
- Module 1.11 Single System REMS vs. Shared REMS Design & Planning

### RIC REMS Education Module 2 - Development

- Module 2.1 Service Provider Oversight
- Module 2.2 Framework and Structure of REMS

What is Coming  
Next?  
Team collaboration  
on remaining  
Modules 2-5 for  
targeted completion  
Dec 2026

<b>2</b>	<b>Development</b>
2.1	Service Provider Oversight
2.2	Framework/Structure of REMS
2.3	Development of Implementation System
2.4	Planning for Assessment Report Rename "Development of Assessment Report"
2.5	Internal Collaborations (Internal Governance/SOP/Budget)
2.6	Contingency Planning
2.7	Launch Readiness
2.8	KAB Surveys
<b>3</b>	<b>General Operations</b>
3.1	Program Management/Inspection Readiness
3.2	Service Provider Management & Audits
3.3	REMS Training for Healthcare Professionals
3.4	REMS Coordinating Center/Database/Website
3.5	Noncompliance Management
3.6	Modifications
3.7	Release of Commitment
3.8	Overview of General Operations (Individual REMS v. Shared REMS)
<b>4</b>	<b>Regulatory (FDA) Interactions</b>
4.1	Understanding Existing Guidances
4.2	Engagement/Expectations
4.3	FDA Information Requests
4.4	Inspection Readiness
4.5	Overview of Regulatory-FDA Interactions (Individual REMS v. Shared REMS)
<b>5</b>	<b>Shared REMS</b>
5.1	Formation (Governance/service providers) (Note to content creators - include info on selecting service providers)
5.2	Reference Technical Conformance Guidance for Shared REMS
5.3	Design and Development
5.4	Sponsor Engagement
5.5	Transition
5.6	General Operations
5.7	Assessment Reports

A group of people are seated at a long wooden table in a bright, modern office or classroom. They are focused on their laptops. The room has large windows in the background, letting in natural light. The overall atmosphere is professional and collaborative.

# REMS Continuing Education Credits

- Working with the Regulatory Affairs Professional Society (RAPS) to obtain Continuing Education Credits (CEUs) for Module 1
- Would be available (for a fee) for members and non-members
- Being reviewed by Board

# Shout Out to the Education Certification WG Super Stars!

Marc Deluca, Tina Latch, **Rebecca Zonin**, Tasha Clark, Tasha Clark, Reema Mehta, Jamie Wilkins, Suzanne McLeod, Jasleen, Carmit Strauss, Erin Kurtz, Crystal Dart, **Komal Shah**, Sheline Way, Priyanka Varia , **Taj Nero**, My-Oanh Nguyen, **Louis Fox**, Kal Elhoregy, Neha Rana, **Terry Francisco**, Remy Fortunato, Aislinn Mulligan, Maire Donovan, Likhitha Konatham, Heather Luna, Linda Quinn



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Thank you!

