WEBINAR SUMMARY

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Medtech Insight

Pharma Intelligence

Identifying MedTech's Hidden Complaints and Adverse Events: The Power of Automated Social Media Monitoring

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KEY TAKEAWAYS

- MedTech companies have an opportunity to harness social data for commercial and clinical insights, as well as patient safety.
- Complaint management is an integral part of a quality management system.
- IQVIA's Vigilance Detect automatically connects social media data with SmartSolve's eQMS.
- Automated social media monitoring solutions keep complaint systems "lean and clean."

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IQVIA TECHNOLOGIES

OVERVIEW

In recent years, the volume of activity on social media has grown and new social platforms are constantly emerging. These communication channels are increasingly important to MedTech companies. Consumers often use social media to share information about potential product complaints and adverse events.

Automated social media monitoring systems are making this data accessible and usable to the MedTech sector. These solutions capture and mine information on social media platforms in near real time, for further assessment and processing, with the goal of improved patient safety and maintaining regulatory compliance, while minimizing the amount of irrelevant data in safety databases and quality management systems (QMS).

CONTEXT

Panelists from IQVIA discussed how IQVIA connected intelligence leverages social media and a quality management system to improve safety and early detection, enhance product surveillance, shorten cycle times by finding issues sooner, and improve regulatory compliance.

KEY TAKEAWAYS

MedTech companies have an opportunity to harness social data for commercial and clinical insights, as well as patient safety.

The MedTech industry is evolving rapidly and facing unprecedented regulatory complexity. The pandemic has prompted an increase in the publication of regulations and guidances. Gathering relevant information is key to developing and maintaining a regulatory strategy.

Unfortunately, many regulatory personnel are bogged down with repetitive manual tasks that distract from more valuable strategic and proactive work. In addition, information silos are commonplace. Teams need easy access to up-to-date information and a knowledge base enabled by technology.

In addition to the dynamic regulatory environment, the safety landscape is also evolving quickly. An ongoing trend is democratization of safety reporting through technology. Reporting adverse events or product dissatisfaction has become mainstream and regulators are encouraging patient and consumer engagement in reporting side effects and issues with products. They are calling for real-world evidence to play a significant role in regulatory decision making. Customer-centric mechanisms of reporting include conversations on social platforms, audio transactions, digital assets like virtual AI agents and wearables, and more.

> Organizations are at a pivotal point of understanding how to harness the growing social data for commercial and clinical insights and for the long-term benefit of patient safety. This extends to complaints and how organizations manage them in this evolving safety and regulatory landscape.
>
> *– Marie Flanagan, IQVIA*

Figure 1. Regulatory Complexity is Growing

Life Sciences Industry is facing unprecedented regulatory complexity

The Regulatory Burden	
357k+ Global National Authority Regulatory Documents[1]	**24k+** New National Authority regulatory documents added per year[1]
70% Of the global requirements are published in the native language (non-English)[1]	**54%** Increase in National Authority documents within the last 5 years[1]
Every 21 Minutes a new or changed National Authority document is published somewhere in the world[1]	

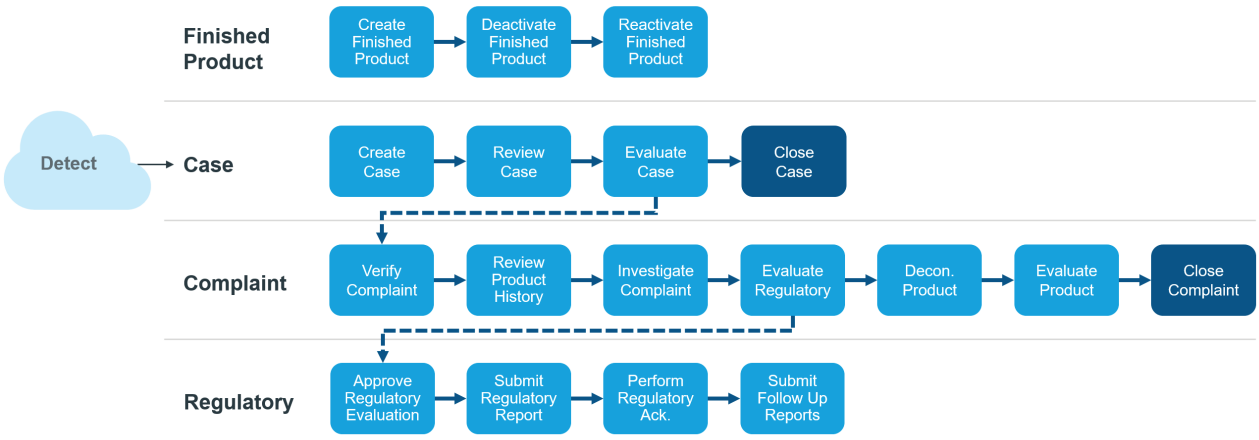
Current Industry Challenges and Needs	
Lack of up-to-date regulatory intelligence	Difficult to keep up to date with regulatory changes at global scale and with local and language expertise
RI tasks can be manual and labor-intensive	RI spends more time on repetitive information requests, and less time on strategic and proactive work
Siloed and Complex systems and technology	Siloed information, systems and technology are inefficient and create knowledge bottlenecks

1 IQVIA Regulatory Intelligence – February 2023

Complaint management is an integral part of a quality management system.

Quality management systems establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Any complaint involving the possible failure of device labeling or packaging to meet specifications must be reviewed, evaluated, and investigated. Complaint management consists of multiple workflows.

Figure 2. Complaint Management Workflows



Companies face a variety of challenges related to complaint management, such as:

- Inconsistency in data and inefficiencies in data processing, since inquiries come from many different, unrelated sources
- Timely awareness of incidents which is needed to satisfy regulatory reporting requirements
- Difficulty understanding global regulatory reporting requirements
- Problems acting on meaningful data for product or process improvements

At a high level, a complaint management system enables users to streamline both complaint handling and regulatory reporting.

Figure 3. Key Functionality in a Complaint Management System

- **Streamline information from disparate sources**
  - Simple forms to record incidents quickly and consistently
  - Case Intake portal enables extended demand chain allowing employees to record incidents in a secure, consistent manner
  - Secure open integration connections allowing for intake from multiple sources
- **Reliable complaint handling process**
  - Incident awareness date and automatic notifications ensure timely regulatory submissions
  - Policies to assign case/complaints to right person(s) based on product type and reporting site
  - Checklists tie procedures and complaint determination criteria to intake process
  - Reduce risk with built-in impact assessments
- **Simplify global adverse event reporting**
  - Bi-directional integration with the FDA's Electronic Submissions Gateway for eMDRs
  - Generation of XML files for reporting to the EU and various other regulatory bodies
  - Finished product information and decision trees ensure accurate regulatory reporting
- **Continuous quality improvement**
  - Identify early signs of sub-par supply chain components
  - Use complaint data to provide critical feedback into design, manufacturing, supplier, and risk management processes

> Complaint management can be used as a tool to support continuous quality improvement by identifying early signs of subpar supply chain components. Complaint data often provides critical feedback into design, manufacturing, supplier, and risk-management processes.
>
> *– Donna Smith, IQVIA*

IQVIA's Vigilance Detect automatically connects social media data with SmartSolve's eQMS.

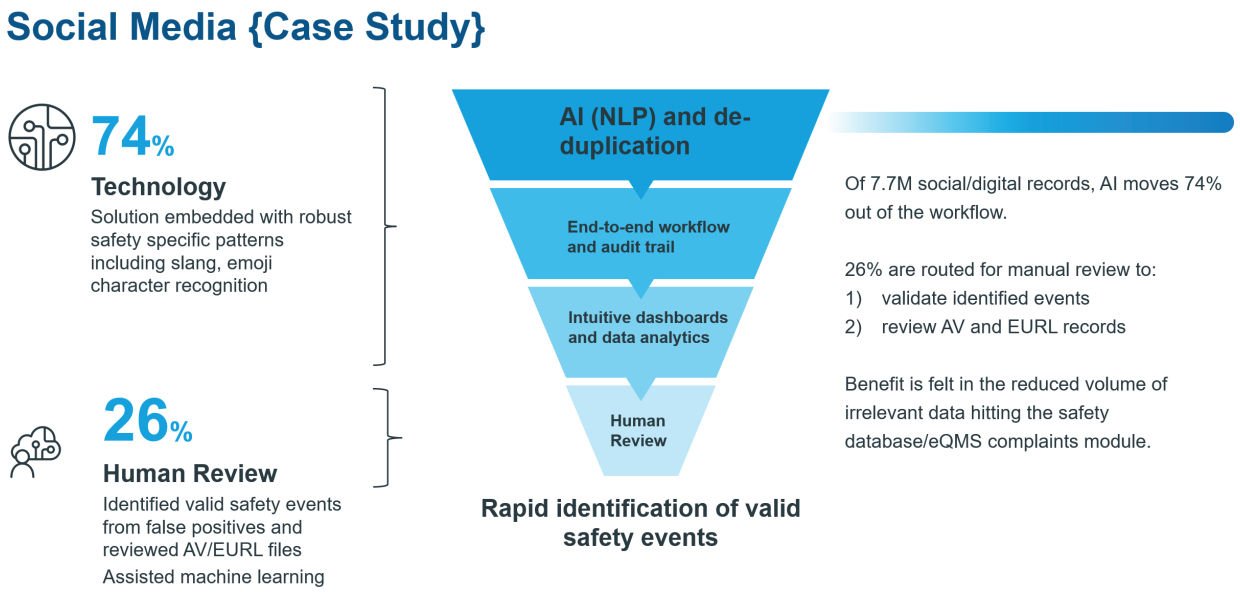
Vigilance Detect automatically identifies potential product complaints and potential adverse events, while removing noise from social data. Relevant information is sent via an integrated workflow to SmartSolve's complaint management module for review and validation. Processing happens within seconds.

> From the moment that someone tweets on a brand page to the time that it appears in the SmartSolve complaint module—that process takes just a few seconds.
>
> *– Sanmugam Aravinthan, IQVIA*

When data is sent to the Vigilance Detect platform from a social media post, it includes mapping to MedDRA (Medical Dictionary for Regulatory Activities) coding. That information can also be sent to SmartSolve.

Clients using Vigilance Detect and SmartSolve see reduced volumes of irrelevant data hitting their safety databases and the eQMS complaints module. Behind the scenes is a GxP-compliant, fully validated solution. The timestamped audit trail demonstrates that organizations proactively reviewed social data and took action when they found something.

Figure 4. IQVIA's Technology Rapidly Identifies Valid Safety Events Within Social Media Data



Automated social media monitoring solutions keep complaint systems "lean and clean."

An effective social media monitoring system has four characteristics:

1. Mature established technology to provide a seamless, integrated workflow
2. Human expertise to combine and connect technology and optimize processes
3. Natural language processing technologies and ontologies customized to the specific product and customer needs
4. A flexible solution that adapts to an evolving landscape

Organizations that deploy automated social media monitoring see benefits in three key areas:

1. **Efficiency.** Professional resources are freed from manual reviews and data updates from social medial channels. Cycle times are shortened, since real issues are found sooner.
2. **Quality.** The "noise" is minimized. In addition, records that require review are separated for human intervention. Safety is improved via early detection and overall compliance.
3. **Future proofing.** Organizations can scale without adding to headcount. Operations are enhanced through better market surveillance and qualitative perspectives.

CONCLUSION

Quality and Regulatory teams in the MedTech sector recognize the power and the challenges associated with social media. These platforms contain important commercial and clinical insights that may be directly related to patient safety. However, unifying information from such an expansive data source is yet another task for overburdened compliance professionals.

Automated social media monitoring tools like IQVIA's Vigilance Detect and SmartSolve streamline data gathering and analysis processes. They reduce the noise associated with social media content, making it easier to rapidly identify potential adverse events and reducing the volume of irrelevant information in eQMS-complaint modules. The result is a GxP compliant and fully validated source of real-world data that supports regulatory compliance and safety surveillance.

BIOGRAPHIES

Sanmugam Aravinthan

Senior Director, Development, Vigilance Detect, IQVIA

As Senior Director, Development of IQVIA's Vigilance Detect (powered by AE Tracker®), Sanmugam's main area of focus is on driving the technology development and delivery of a productized solution that enables optimized approach in detecting adverse events, product quality complaints and other safety risks in large-scale structured and unstructured data. He has 20+ years of industry experience in driving Software Engineering and Systems Development, with the past 10 years in pharma and life sciences specifically. He has got a strong track record in directing software product development, managing technology delivery of clients and leading pharmacovigilance operations in client implementations. He has a US patent titled "System and method for multi-dimensional profiling of healthcare professionals."

Marie Flanagan

Director, Offering Management, Vigilance Detect, IQVIA

As Director, Offering Management, of IQVIA's Vigilance Detect (powered by AE Tracker®), Marie's focus is on developing the Detect portfolio and ensuring the offerings meet client and regulatory needs.

Marie joined Quintiles Drug Safety over 17 years ago. In her tenure, Marie has successfully held many leadership positions in operations and project management and leveraged learned skills and competencies across a broad spectrum of pharmacovigilance (PV) services. In 2017, as the Global Head of PV Services Integration, Marie led a team of PV Product Specialists that focused on the strategic expansion efforts of IQVIA's PV department, conducting PV landscape assessments and analyzing emerging trends. Throughout the years, she has supported Global Business Operations, Strategic Pricing, Business Development, PV Operational Management and the integration of Safety Technology and Services.

Marie graduated from University College Cork, Ireland with an MSc in Medical Microbiology. In 2021, she joined the Vigilance Detect team, leveraging her 17+ years of safety experience.

Donna Smith
Product Manager, Product Management, Quality Solutions, IQVIA

As a Product Manager supporting IQVIA's Quality Compliance Solutions, Donna is responsible for product planning and execution throughout the software development lifecycle, while ensuring that delivered products meet best practices and support the company's overall strategy. Donna is responsible for defining requirements for product enhancements, new products, and third-party product integrations for multiple modules within the SmartSolve suite of solutions, including Complaints Management, Supplier Management and Risk Management.

Donna has more than 25 years of experience in enterprise software development with 4+ years focused on Life Sciences. She brings that knowledge to her role as Product Manager, focusing on translating market and industry requirements into industry-leading enterprise quality management solutions that meet the needs of the heavily regulated life sciences QMS market. Donna has a Bachelor of Science in Management Information Systems from Pace University in New York and an MBA with a concentration in Management Information Systems from the University of Arkansas.