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Safety Communications: Enabling Clarity

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EXECUTIVE SUMMARY

In an increasingly complex regulatory and scientific environment, the ability to communicate safety and benefit–risk information clearly and consistently is not just a compliance requirement; it is a strategic imperative. This white paper explores how leading biopharmaceutical organizations are rethinking their safety communication frameworks to drive clarity, alignment, and operational excellence. Drawing on recent project experience and industry best practices, we outline key challenges, emerging trends, and the value of expert-led transformation enabling the pharmacovigilance mantra of protecting patients.

This paper also highlights the importance of aligning internal processes with global regulatory expectations, and how organizations can leverage structured frameworks, digital tools, and cross-functional collaboration to improve safety communication outcomes. By investing in strategic transformation, companies can enhance regulatory compliance, reduce operational risk, and build trust with stakeholders across the healthcare ecosystem.

Introduction

Safety and benefit–risk communication is a visible, cross-functional activity that shapes regulatory outcomes, stakeholder trust, and ultimately, patient safety. Yet many organizations still operate with fragmented processes, inconsistent terminology, and reactive workflows.

As the volume and complexity of safety data increase, so does the need for timely, accurate, and coordinated communication. When responding to emerging safety signals, organizations must ensure that their messages are aligned, traceable, and compliant with global standards.

Organizations that treat safety communication as a strategic capability, rather than a compliance checkbox, are better positioned to respond to emerging risks, regulatory scrutiny, and global market demands in a time-constrained duration.

Current State of Play

From consulting experience working across many different pharmaceutical/biotech companies we discovered a lack of standardization in safety communication practices which included: non-standard, company-wide terminology, no clear ownership of the process and inconsistent working timeframes. Only a few organizations have a centralized tracking system or governance model, all fueled by global regulations that are open to interpretation.

Some companies rely heavily on manual processes and email-based coordination, while others have begun to implement digital collaboration platforms. However, even among more advanced organizations,

there is often ambiguity around roles and responsibilities, especially when communications span multiple regions or product types.

Despite best intentions, many organizations face persistent challenges in safety and benefit–risk communication. As consultants, the main pain points we face when working to improve the process include:

Fragmented Processes
Disconnected workflows across regions and therapeutic areas lead to inconsistent messaging and delays.

Ambiguous Roles and Responsibilities
Lack of clarity on who owns what part of the process results in duplication or missed steps.

Inconsistent Terminology
Without a shared taxonomy, teams may interpret communication categories differently, increasing the risk of non-compliance.

Manual Tracking and Documentation
Reliance on spreadsheets and email chains makes it difficult to ensure traceability and audit readiness.

Limited Cross-Functional Engagement
Key stakeholders are often brought in too late, reducing the quality and alignment of communications.

Regulatory Misalignment
Internal processes may not reflect the latest global regulatory expectations, leading to rework or findings.

With increasing regulatory expectations and internal complexity, the cost of misaligned or delayed safety communication is rising. Forward-thinking organizations are recognizing the need for harmonized processes, discrete terminology, clear roles, and digital collaboration tools.

The consequences of poor communication can include regulatory findings, reputational damage, and delays in product development or commercialization and the obvious real risk to patient safety and their continued wellbeing. Conversely, organizations that invest in proactive communication strategies are better positioned to manage risk, respond to change, and maintain stakeholder confidence.

> "The most successful transformations are not just about process redesign, they are about mindset shift. Embedding a culture of proactive, transparent communication is key to long-term success."

Where the Industry Is Going

While every organization's needs are unique, a strategic framework typically includes defined communication categories, decision-making criteria, timelines, clear ownership and governance structures. It also integrates with regulatory requirements and leverages digital platforms for collaboration and tracking.

Key components of a robust framework include:

- Clear ownership of the process around safety communications
- Defined roles and responsibilities across functions
- A taxonomy of communication types (e.g., urgent vs. non-urgent, investigational vs. marketed products)
- Standard operating procedures and work instructions
- Templates and tools to support consistency
- A centralized collaboration and tracking system

Summary of Regulatory Guidelines

Global regulators such as EMA, FDA, MHRA, and PMDA use varying definitions and timelines for safety communications. A harmonized internal process must be flexible enough to meet these diverse requirements while maintaining consistency and speed.

For example, the EMA requires notification of post-market urgent safety communications (emerging safety issues) within 3 working days, while the FDA may require consultation prior to formal notification of an emerging safety issue (ESI) to discuss the nature and source of the ESI, communication plan and the content of the communication letter. Organizations must be able to navigate these nuances without compromising clarity or compliance.

A well-designed internal process anticipates these differences, understands local nuances and local legislative requirements and provides clear guidance on how to adapt communications for each regulatory context.

The following tables highlight the different terminology and timelines found in local and global legislation that should be considered when creating an internal process.

Urgent clinical trial safety communications

Agency	Terminology	Timeline
EMA (EU)[1]	Urgent Safety Measure	• "Without undue delay" • +7 days after implementation to notify EMA
FDA (USA)[2]	Urgent Safety Measure	• "Promptly"
TGA (Australia)[3]	Significant Safety Issue (SSI)	• Within 72 hours
MHRA (UK)[4]	Urgent Safety Measure	• Phone call within 24 hours • F/U report within 3 days
ANSM (France)[5]	Urgent Safety Measure	• Notification within 24 hours of USM implementation • F/U report within 15 days
PMDA (Japan)[6]	Yellow Letter (emergent & important safety information)	• Not defined

Regulatory agencies use different terms, but all identify the need for urgent clinical trial safety communications to be distributed quickly. Urgent Safety Measure is the mostly commonly used term across agencies for the necessary action needed to be taken. Every regulatory agency shares the principle that on identification of urgent measures the Market Authorization Holder (MAH) should first communicate to the impacted study sites and investigators and subsequently notify agencies as soon as possible after the implementation of the urgent safety measure(s) in a **"Do and Tell"** process.

Non-urgent clinical trial safety communications

Agency	Terminology	Timeline
EMA (EU)[1]	Unexpected event	• 15 days to notify EMA following sponsor awareness
FDA (USA)	(*)	• Not defined
TGA (Australia)[3]	Other Safety Issue (OSI)	• Notification within 15 calendar days
MHRA (UK)	(*)	• Not defined
ANSM (France)	(*)	• Not defined
PMDA (Japan)[7]	Blue Letter (non-emergent but should be provided promptly)	• "Promptly"

** No specific local regulations, follows or refers to EMA guidelines*

Non-urgent clinical trial safety communication requirements differ more than urgent communications. There is no commonly used term across the agencies and timelines are often not specified hence, the importance of having an internal process to harmonise the creation of non-urgent clinical trial safety communications in order to maintain oversight of content and distribution requirements.

Urgent post-market safety communications

Agency	Terminology	Timeline
EMA (EU)[7]	Emerging Safety Issue	• ASAP but within 3 working days
FDA (USA)	(*) Emerging Safety Issue	• Not defined
TGA (Australia)[8]	Significant Safety Issue	• ASAP but within 3 calendar days
MHRA (UK)[9]	Emerging Safety Issue	• Within 3 working days
ANSM (France)[10]	Emerging Safety Issue	• ASAP but within 3 working days
PMDA (Japan)	Yellow Letter (emergent & important safety information)	• Not defined

** No specific local regulations, refers to EMA guidelines*

Regulatory agencies use different terms but all identify the need for urgent post-market safety communication promptly and generally within 3 working days. The most commonly used term is Emerging Safety Issue.

In the post-market setting the regulatory agencies are informed about the emerging safety issue before the communication is distributed to the healthcare professional population. It is a **"Tell and Do"** process with many regulatory agencies requesting to be consulted on the content of the communication and inputting into the scope of distribution prior to dissemination to prescribing healthcare professionals.

Non-urgent post-market safety communications

Agency	Terminology	Timeline
EMA (EU)[11]	Direct Healthcare Professional Communication (DHPC)	• Not described. • But competent authority requires a minimum of 2 days for review of DHPC
FDA (USA)	*Not specified*	• Not defined
TGA (Australia)[12]	Other Safety Issue (OSI)	• Notification within 30 calendar days
MHRA (UK)	DHPC	• In line with EMA (GVP module XV)
PMDA (Japan)[6]	Blue Letter (non-emergent but should be provided promptly)	• "Promptly"

Non-urgent post-market safety communication requirements differ more than urgent communications. There is no commonly used term across the agencies and the timeframe expectation is "without undue delay". Whilst possibly being an infrequent occurrence an internal process for the creation and distribution of non-urgent, post-market safety communications, would mandate and standardise the necessary activities in order to fulfil the regulatory requirements for consultation and dissemination.

Keys to Success

Implementing a new safety communication process requires more than documentation. It requires C-suite sponsorship and involves cross-functional stakeholder engagement, training, change management, and digital enablement.

Key success factors include:

- Clear ownership of decision making to sanction creation and distribution of a safety communication letter at a governance level
- Early and ongoing involvement of cross-functional stakeholders
- Clear communication of the rationale and benefits of the new process
- Tailored training and support materials
- Integration with existing systems and workflows

- Metrics to track adoption and impact

Safety communication is a strategic lever for biopharmaceutical organizations. Those who invest in clarity, consistency, and capability-building will be better equipped to navigate regulatory complexity, protect patient trust and ultimately ensure patient safety whilst receiving company product.

The time to act is now.

As regulatory scrutiny intensifies and stakeholder expectations evolve, organizations must move beyond reactive compliance and embrace a proactive, strategic approach to safety communication.

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