

Cutting Through the Chaos of Safety Letter Distribution

How an automated, unified technology solution helps sponsors and sites manage costs, streamline workflows and ensure compliance.

As clinical trials grow more complex, sponsors must develop effective strategies to manage the higher volume of safety letters that this complexity may generate.



HOWEVER, DISTRIBUTING MORE SAFETY LETTERS COMES WITH SIGNIFICANT LOGISTICAL CHALLENGES.

Including an increased burden on sponsors to:

- Manually deliver (or distribute) safety letters via email or mail.
- Comply with diverse global regulatory guidelines to prevent over- or under-distribution.
- Manage audit trails for effective safety letter distribution.

MANUAL PROCESSES COMPLICATE WORKFLOWS AT SITES, TOO.

- Site staff must devise systems to self-manage safety letters within their email platform — including multiple letters for the same study.

As the volume of safety letters increases, it becomes near impossible for site staff to translate safety information into informed care.

13% of medication safety letter recipients remember receiving them.¹



OUTSOURCING SAFETY LETTER MANAGEMENT TO A CRO MAY FURTHER COMPOUND THE PROBLEM.

While CROs have systems in place to manage safety letter distribution, these processes can differ significantly from CRO to CRO. This results in:

- **For sites:** Confusing workflows increase the potential for error.
- **For sponsors:** Siloed safety letter with limited access to portfolio-level compliance data.

Automated Solutions Help Streamline Safety Letter Distribution

An effective safety letter distribution solution allows sponsors to manage safety letter assignments, notifications, and acknowledgements in one place, offering support along the life cycle of each letter.



Sending

Instead of...

having to manually compile a list of safety letter recipients, double-checking to avoid over- or under-distribution, sponsors and CROs can:

- **Automatically send safety letters to the appropriate recipients in compliance with local regulations.**



Receiving

Instead of...

having to find important safety letters among the other correspondence in their email platform, sites can:

- **Avoid redundant notifications and consolidate safety letters in one unified solution.**



Acknowledging

Instead of...

having to find the appropriate workflow to acknowledge a safety letter to the appropriate part (e.g. each individual sponsor/CRO), sites can:

- **Acknowledge at the compound level, eliminating redundant acknowledgements.**
- **Easily track acknowledgements (and identify unacknowledged letters) to maintain compliance.**



Tracking Compliance

Instead of...

having to manually compile safety letter data from multiple CROs to gain unified insights into compliance, sponsors can:

- **Monitor compliance across all sites in real time, using one unified platform.**
- **Identify underperforming sites quickly and take the appropriate next step.**
- **Continue to task multiple CROs with monitoring responsibilities within the single platform.**

The Results

FOR SPONSORS:

- ✓ Lower costs from fewer labor-intensive manual workflows.
- ✓ Less risk of over- or under-delivery.
- ✓ Real-time visibility into global compliance.

FOR SITES:

- ✓ Efficient, streamlined workflows.
- ✓ Reduced burden on site teams.
- ✓ Streamlined acknowledgements at the compound or site level.

Bring Safety Letter Management Chaos to Order

Streamline each step of safety reporting and ensure compliance across all sites with WCG's Safety Letter Distribution solution.

10 million+

safety letters distributed annually.

100%

auditability and traceability with a complete audit trail.

250+

global markets supported, covering all recognized countries as well as territories and island regions.

[Learn More](#)

References:
1. <https://pmc.ncbi.nlm.nih.gov/articles/PMC6194396/>