

Looking to Simplify Your Safety Notifications Process? Consider a Cross-Trial SaaS Solution

Why new centralized SaaS solutions make more sense than ever before



Brian Fisher,
President,
Trial Management
at DrugDev

A traffic-light is out of service during rush hour in a busy city intersection. To prevent accidents, a police officer is there directing traffic. Suddenly, three more show up, each directing traffic for their own respective lanes. After some time, the police mix signals and an accident occurs. Confused motorists ask themselves “why didn’t they just use a single cop?” while others bemoan the loss of the traffic light.

To many, the inherent risk in the above scenario is obvious. However, this is the same risk still seen today with sponsors and CROs who use multiple systems or manual processes for safety notifications. Their method usually involves managing and combining many moving parts. While this has the potential to be a well-controlled process, it often leaves a large amount of room for error.

Recently, some larger sponsors, such as Novartis, have been pioneering the use of cross-trial systems that allow the dissemination, tracking, and documentation of safety notifications from a single-dashboard. In fact, DrugDev and a top-5 sponsor recently worked together to create the industry’s simplest centralized safety notifications solution. After piloting this system together, one thing’s clear – cross-trial systems simplify everything, providing the centralization needed to effectively and easily manage the safety process.

Why Choose Cross Trial?

It’s simple. A cross-trial system allows sponsors and CROs to control every aspect of the safety notification process from a single dashboard, removing the

need to independently manage and combine multiple moving parts. This includes:

- Disseminating safety notifications to all relevant site personnel who are affected by an adverse compound, regardless of trial differences, country differences, etc.
- Managing the receipt, acknowledgement, and tracking of safety notifications
- Keeping a comprehensive audit trail of each document, notification, acknowledgement, and more
- Identifying which site personnel are still outstanding for receipt and acknowledgement of safety notifications allowing study teams to follow up

The impact of these features allows sponsors to reduce costs, save time, and mitigate some of the liability around audits and safety errors.

Cost Reduction

For sponsors who manage their process electronically, a cross-trial system cuts down on costs by reducing the number of systems that must be managed, paid for, and serviced by consolidating all these processes. This has a large impact on “man hours,” especially during audits, when records must be found, pulled, and properly assembled.

For the many who still use paper, a cross-trial system has the potential to save millions of dollars by eliminating printing costs, shipping costs, labor payments, and more.

Time Savings

Cross-trial systems also help save time. Simply put, the ability to push out notifications to all required personnel from one dashboard no matter the trial, country, or role tremendously reduces the amount of time that safety notifications require. In the past, sponsors had to push out each notification separately based on the trial,

country, or other factors. Then, they would need to separately track receipt and confirmation of safety notifications. Often, this involved multiple study staff coordinating their work across multiple systems. With cross-trial solutions, these problems are removed.

Greater Audit Compliance and Increased Transparency

A cross-trial system also reduces the number of audit findings by providing an expert level of transparency and centralization. Centralized systems track each safety notification from the moment it is selected for dissemination, to the moment it is acknowledged by the site staff. This includes all updates to the documents, all channels that the document passed through, time-stamps, and more. This automatic tracking allows study teams easy and instant access to the electronic records in the event of an audit while eliminating the need to manually log and document each outreach and acknowledgement.

Reduced Liability

The automatic tracking and of acknowledgement of each notification also cuts down on potential legal liability. No longer are there lingering questions of whether an investigator or site staff read a safety notification, as this is automatically logged and timestamped as soon as the individual has completed acknowledgement.

Worth the Risk of Waiting?

With the new breed of cross-trial safety notification systems becoming more prevalent, sponsors and CROs must now ask themselves whether the inherent risks presented by their current processes are worth it. After all, there are very few who would argue for multiple police officers in one intersection. ●