THE FOUR TAKEAWAYS

Relieving the Safety Reporting Burden on Sites

In a highly competitive market, some sponsors are alienating sites and investigators by wasting their time. To reduce the burden on sites, sponsors must rethink how they manage safety reporting.

Of course, investigators must be kept informed of safety issues throughout the trial, but inundating them with unnecessary and duplicative reports is counterproductive. A review of nine years of safety reports by oncology sites, found that:

86%
of all safety letters were uninformative or unnecessary

→

54%
did not meet FDA "expectedness" criteria

→

50%
did not meet FDA casuality criteria[1]

It's a costly problem with profound implications for compliance, site relations and patient safety. In a recent WCG webinar, Elena Jouravleva, PhD, Director of Regulatory for US Oncology Network, and Steven Beales, WCG's Senior Vice President, Scientific and Regulatory, discussed these issues, with particular emphasis on the burden placed on oncology sites.

[1]Jonathan Jarrod and Sean Khozin, FDA 2015

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THE FOUR MAJOR TAKEAWAYS

1

Overdistribution can cost sponsors access to top-level sites

Some sites now refuse to work with certain sponsors because of the onerous safety-reporting burden. Even if they don't blacklist those sponsors, sites have become more selective. It's a competitive landscape in oncology, with more trials than patients. As sites and site networks evaluate which studies to move forward with, one key consideration will be the level of administrative burden—especially in terms of SUSAR distribution. Sponsors that excel at communicating with sites and distributing SUSARS will have a distinct advantage.

2

Over distribution puts patients at risk

When sponsors bombard sites with often-unnecessary safety notifications, the sites risk being overwhelmed to the point where they miss the critical patient-safety information. The SUSARs and other reports become a nuisance instead of being actionable and important documents. As a result, sites are pushing back and are refusing to process events that are not identified and labeled as SUSARs. Sites need to know whether the reports they are receiving are directly applicable to their patient care.

3

Oncology is already overwhelmed

In oncology, it can be difficult to determine whether an event is being caused by the underlying disease or is related to the therapeutic being tested. The FDA doesn't want the sponsors to overreact to the first event if it's something prevalent in the population being studied. But some sponsors are sending out multiple SUSARs related to the same event—an event that may not be serious or caused by the therapy.

4

Portals are the future

Yes, technology can be frustrating, but the alternative is worse. Mail, CDs, faxes, hand delivery by monitors, etc. are even more time consuming. Portals minimize the time that investigators and staff need to spend away from a patient while making sure all of the valuable safety signals get through. A good portal should be built with sites in mind, making it a streamlined, less cumbersome process.

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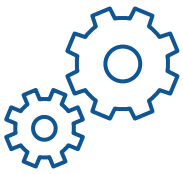
THE KEY ABILITIES PORTALS SHOULD HAVE

Make it easy to acknowledge and delegate

The optimum flow we found to minimize the site's time is to send an email with a link in it. Then staff can read the full text or the summary. The system records this without any action from the PI. (Remember, the FDA does not require PIs to sign individual SUSARs.) It also allows the PI to delegate as needed.

Batch and summarize notifications

Don’t send out individual notifications: Batch them according to the site’s preference. Include an executive summary at the beginning to make review easier; don’t force investigators to read through eight pages of text.



Deliver SUSARs at the compound level

SUSARs typically go out at the study level, rather than the compound level. This can be overwhelming in oncology, particularly for successful drugs such as PD-1 checkpoint inhibitors. We’ve been seeing a five-fold increase in SUSAR distribution, much of which is duplicative. Just as important, the platform must allow investigators to acknowledge the notice at the compound level.

At the end of the day, we're just using this technology to improve patient care and to improve the experience of PIs and sites. We hear a lot of lip service given to being a “sponsor of choice” and listening to sites, but very few organizations are putting that into practice.

It gets back to a simple question: Why are we doing this? To show the FDA that we’ve checked off the right boxes, or so that we are truly improving patient care?

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