

# Drug Safety in Biotech

Fewer potential new drugs, fewer mass market opportunities, candidate drop out, declining returns...just some of today's pressures on life science companies. If only there was a way to solve the conundrum of maximising ROI as opportunities decline. Now, there is!



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## Under-used asset

There is an asset all biotech companies have. It represents a large investment – and few of them are exploiting it to the full. That asset is their investment in pharmacovigilance (PV). Integrate PV with your core activity and you can produce developments that are easier to licence, swifter to market, quicker and more predictable in uptake, assuring your future funding.

Two key lessons emerge from all-too-well-known industry mistakes. First, you need a 'fit for purpose' PV system to protect your portfolio asset. It must provide you with the data, from every possible AE source, that enables you to avert potential post launch disasters long before they happen. Second, your company must speak with one voice – a seamless, synchronous, global, stance on all safety matters.

## No surprises!

To earn its keep, PV must do more than avoid compliance problems. Safety issues after launch can wipe millions off share values – and market share. When you launch, you must be confident that there will be no surprises. Safety data, organised, collected and available at the click of a mouse, will contribute crucially to 'go/no-go' decisions – at every decision point in the Clinical Development process. Compliance data becomes a high- quality, integrated component of the process.

Your PV systems are key to keeping up with the business need, adapting to new approaches and applications. They flag up potential safety risks so that you can plan in time to mitigate their effects. Integrated, scaleable and auditable using standard metrics, they are robust and consistent – across geography, across the enterprise and into the future.

## One voice

Maintaining 'one voice' on safety matters – to regulators, markets and investors too – is business critical. Manage product safety risks proactively, lay down an iron-clad communication plan for the quick, safe and effective management of safety issues seamlessly across company interfaces.



Simplify what you do

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## Simple solution

Get the fundamentals right first and remember that 'simple is effective'! With comprehensive, timely, accessible data, decisions and ideas are in line with hard evidence; future investments are planned using consistent criteria. At the hub is a globally accessible on line AE database.

## Strategy

The approach reflects a strategy of protecting assets, patients and products, anticipating issues proactively to maintain regulatory compliance and minimise business risk.

The PV system is key to the development, introduction and marketing of new drugs and therapies, and inputs to investment decisions. It uses universal, visible, best practice, metrics and feedback that are clear, robust and documented. Regulatory compliance and risk management are a company responsibility – a global Drug Safety Management role owns AE data, PSUR and Signal Management. Safety investment is proportionate, based on product risk profiles.

## Integration works

PV, integrated but not absorbed, is at least a part of, rather than apart from, core business process. Making the most of PV data lifts current pressures and spotlights new opportunities. World class pharmacovigilance adds value, not cost.



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